Table of Contents

Actemra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-111071
Guideline Name	Actemra
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of moderately to severely active Rheumatoid Arthritis (RA)

AND

1.2 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.3 Patient is NOT receiving Actemra in combination with any of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)**
- Enbrel (etanercept)**

AND

1.5 Prescribed by, or in consultation with, a rheumatologist

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

2.1 Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Patient is NOT receiving Actemra in combination with any of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by, or in consultation with, a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **Drug may require PA.

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to both of the following:

- Humira (adalimumab)*

- Enbrel (etanercept)*

OR

2.2 Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Actemra in combination with any of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by, or in consultation with, a rheumatologist

Notes	*May require PA

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Patient is NOT receiving Actemra in combination with any of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis (PJIA), Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

2 - Patient is NOT receiving Actemra in combination with any of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra Actpen, Actemra SQ

Diagnosis	Giant Cell Arteritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of giant cell arteritis

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to ONE glucocorticoid (e.g., prednisone)

OR

2.2 Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Actemra in combination with any of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra Actpen, Actemra SQ

Diagnosis	Giant Cell Arteritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

2 - Patient is NOT receiving Actemra in combination with any of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of active systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10% of the lungs

AND

2 - Patient is NOT receiving Actemra in combination with any of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a pulmonologist

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

2 - Patient is NOT receiving Actemra in combination with any of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a pulmonologist

Acthar Gel, Cortrophin Gel

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110580
Guideline Name	Acthar Gel, Cortrophin Gel
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Acthar Gel	
Diagnosis	Infantile spasm (i.e., West Syndrome)*
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infantile spasms (i.e., West Syndrome)*

AND

2 - Patient is less than 2 years old

AND **3** - Both of following: **3.1** Initial dose: 75 units per meters squared intramuscular (IM) twice daily for 2 weeks **AND** **3.2** After 2 weeks, dose should be tapered according to the following schedule: 30 units per meters squared IM in the morning for 3 days; 15 units per meters squared IM in the morning for 3 days; 10 units per meters squared IM in the morning for 3 days; 10 units per meters squared IM every other morning for 6 days (3 doses)

Notes	*Note: Acthar Gel is not medically necessary for treatment of acute ex acerbations of multiple sclerosis.

Product Name: Acthar Gel, Cortrophin	
Diagnosis	Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*

AND

2 - For Cortrophin requests ONLY: Trial and failure or intolerance to Acthar Gel (verified via paid pharmacy claims or submission of medical records/chart notes)

Notes	*Note: Acthar Gel is not medically necessary for treatment of acute ex acerbations of multiple sclerosis.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Actimmune

Prior Authorization Guideline

Guideline ID	GL-110636
Guideline Name	Actimmune
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic granulomatous disease	

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, malignant osteopetrosis

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Actimmune will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Actimmune therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Adacel TDAP vaccine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125631
Guideline Name	Adacel TDAP vaccine
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Adacel	
Diagnosis	Pregnant Patients 19 years of age and older*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Vaccine is being used to prevent pertussis in infants younger than 2 months of age

AND

2 - Patient is 19 years of age or older

AND **3** - Both of the following: • Patient is pregnant • Vaccine is being administered during 3rd trimester of pregnancy	
Notes	*Patients under 19 years of age must get immunization from PCP or p ediatrician through the VFC (Vaccines For Children) Program

2 . Revision History

Date	Notes
5/11/2023	Matching FFS

Adakveo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110640
Guideline Name	Adakveo
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Adakveo	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sickle cell disease, identified by any genotype

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Age 16 to 20 years
- Prescriber attests the service is medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness in an eligible patient

OR

2.2 Age greater than or equal to 21 years

AND

3 - Patient has experienced at least two vaso-occlusive crises within the past 12 months

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Adbry (tralokinumab-ldrm)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-122727
Guideline Name	Adbry (tralokinumab-ldrm)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Submission of documentation (e.g., chart notes) demonstrating one of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - History of failure, contraindication, or intolerance to BOTH of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole) ointment

AND

6 - Trial and failure of a minimum 12-week supply, intolerance, or contraindication to Dupixent (dupilumab) for the treatment of atopic dermatitis

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and/or contraindication to medication

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) demonstrating positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05

	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes

3/10/2023	Updated embedded step requirements

ADHD Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137416
Guideline Name	ADHD Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Brand Adderall, generic amphetamine/dextroamphetamine, Brand Adderall XR, Brand Concerta, Brand Daytrana, generic dexmethylphenidate tabs, Brand Focalin XR, Brand Methylin, generic methylphenidate tabs, Brand Ritalin LA, methylphenidate CD/ER caps, Vyvanse caps, generic atomoxetine, generic dextroamphetamine tabs, Adhansia XR, Adzenys XR-ODT, generic amphetamine tabs, generic amphetamine/dextroamphetamine ER, Brand Aptensio XR, Azstarys, Cotempla XR-ODT, Brand Desoxyn, Brand Dexedrine, generic dexmethylphenidate ER, generic dextroamphetamine ER, Dyanavel XR, Evekeo ODT, Brand Focalin, Jornay PM, generic methamphetamine, methylphenidate ER tabs, generic methylphenidate ER (OSM), Methylphenidate ER (OSM), generic methylphenidate ER (LA) caps, generic methylphenidate ER (XR) caps, Mydayis, Brand Procentra, Qelbree, Quillichew ER, Quillivant XR, Relexxii, Brand Ritalin, Brand Strattera, Vyvanse chew, Zenzedi, generic dextroamphetamine oral soln, Brand Evekeo, generic methylphenidate patches/soln, methylphenidate chew tabs, amphetamine ER, Adzenys ER, lisdexamfetamine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the patient is under 6 years old, ALL of the following:

1.1 The requesting clinician has documented that the child has a diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

1.2 The requesting clinician has documented that psychosocial issues have been evaluated before request for ADHD medications

AND

1.3 The requesting clinician has documented non-medication alternatives that have been attempted before request for ADHD medications

AND

1.4 The requested dose does NOT exceed the Food and Drug Administration (FDA) recommended maximum daily dosage unless the provider has submitted clinical justification for the dose exceeding the FDA maximum

AND

2 - If the request is non-preferred*, the patient has a history of failure, contraindication, or intolerance to a trial of FOUR preferred products**

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP **Alternatives may require prior authorization.

Product Name: clonidine tabs, generic clonidine ER 12 hr, guanfacine, generic guanfacine ER, Brand Intuniv, Brand Kapvay	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - If the patient is under 6 years old, ONE of the following:

1.1 ALL of the following:

1.1.1 The requesting clinician has documented that the child has a diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

1.1.2 The requesting clinician has documented that psychosocial issues have been evaluated before request for ADHD medications

AND

1.1.3 The requesting clinician has documented non-medication alternatives that have been attempted before request for ADHD medications

AND

1.1.4 The requested dose does NOT exceed the Food and Drug Administration (FDA) recommended maximum daily dosage unless the provider has submitted clinical justification for the dose exceeding the FDA maximum

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of insomnia

AND

1.2.2 Trial and failure, contraindication, or intolerance to melatonin

AND **2** - If the request is non-preferred*, the patient has a history of failure, contraindication, or intolerance to a trial of FOUR preferred products**

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP **Alternatives may require prior authorization.

Product Name: Xelstrym	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is non-preferred*, the patient has a history of failure, contraindication, or intolerance to a trial of THREE preferred products**

AND

2 - The patient has a history of failure, contraindication, or intolerance to Daytrana

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP **Alternatives may require prior authorization.

2 . Revision History

Date	Notes
12/6/2023	Added new GPIs for Relexxii. Updated product name of first section to add Methylphenidate ER (OSM).

Aduhelm (aducanumab-avwa)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-111620
Guideline Name	Aduhelm (aducanumab-avwa)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Mild cognitive impairment (MCI) due to Alzheimer's Disease (AD)
- Mild dementia due to Alzheimer’s Disease (AD)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values, examination histories) documenting the basis for diagnosis, including all of the following:

2.1 Documentation of a comprehensive history and neurological examination, inclusive of a description of the nature and duration of cognitive symptoms within the previous 3 months

AND

2.2 Medical records documenting baseline (within the previous three months) cognitive function based on ONE of the following objective assessments:

- Mini-Mental State Examination (MMSE) score greater than or equal to 24
- Montreal Cognitive Assessment (MoCA) score greater than or equal to 15

AND

2.3 Medical records documenting confirmed evidence of clinically significant AD neuropathology based on ONE of the following:

- Cerebral Spinal Fluid (CSF) biomarkers
- Amyloid positron emission tomography (PET)

AND

3 - Patient has received recent (within the previous 3 months) baseline brain magnetic resonance imaging (MRI) prior to initiating treatment

AND

4 - Patient does NOT have significant cerebrovascular disease as established by brain MRI showing any of the following:

- Acute or sub-acute hemorrhage
- Prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage)
- 4 or more brain microhemorrhages
- Cortical infarct

- More than 1 lacunar infarct
- Superficial siderosis
- History of diffuse white matter disease

AND

5 - Patient does not have any of the following non-AD neurodegenerative disorders:

- Probable dementia with Lewy bodies by consensus criteria
- Suspected frontotemporal degeneration
- Dementia in down syndrome

AND

6 - Patient does not have any of the following exclusionary neurological or psychiatric conditions:

- Uncontrolled seizure disorder
- Uncontrolled mood disorder, anxiety disorder, or psychosis
- Substance use disorder active in the past 2 years

AND

7 - Patient does not have any of the following cardiovascular conditions:

- Uncontrolled hypertension
- Coronary artery disease (including unstable angina and myocardial infarction)
- Heart failure
- Arrhythmia
- Clinically significant carotid atherosclerosis and/or peripheral arterial disease

AND

8 - Both of the following:

- Patient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 milligrams/day or less)
- Patient has no history of transient ischemic attack (TIA), stroke, or unexplained loss of consciousness within the previous year prior to initiating treatment

AND

9 - Patient does not have any uncontrolled clinically significant chronic medical condition [e.g., liver disease, kidney disease, pulmonary disease, autoimmune disease requiring chronic immunosuppression, malignant neoplasm, active chronic infection (HIV, HCV), poorly controlled diabetes mellitus]

AND

10 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

11 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatrics specialist

AND

12 - Prescriber attests that the patient and/or authorized representative (e.g., power of attorney, invoked health care proxy) has shared in decision-making and has been informed on the known and potential risks and lack of established clinical benefit associated with Aduhelm (aducanumab-avwa) treatment

AND

13 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had greater than or equal to 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)
- If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity]

- If the patient has had greater than or equal to 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

2 - Follow-up MRIs (magnetic resonance imaging) have been conducted at the following timeframes:

- Week 14 [after 4th infusion, prior to first 6 mg/kg (milligrams/kilogram) dose]
- Week 22 (after 6th infusion, prior to first 10 mg/kg dose)
- Week 30 (after 8th infusion, prior to third 10 mg/kg dose)
- Week 42 (after 11th infusion, prior to sixth 10 mg/kg dose)
- Every 6 months thereafter

AND

3 - Patient’s diagnosis continues to be mild cognitive impairment or mild dementia stage due to Alzheimer’s disease as established by one of the following examination scales:

3.1 One of the following:

- Mini Mental State Exam (MMSE) score greater than or equal to 24
- Montreal Cognitive Assessment (MoCA) score greater than or equal to 15

OR

3.2 Both of the following:

- MMSE < 24 or MoCA < 15
- Rate of decline was slower than expected (less than 2 points/year)

AND

4 - ONE of the following [ARIA-H (amyloid related imaging abnormalities - haemosiderin), microhemorrhages]:

- Patient has had no new incident microhemorrhage
- Patient has had 1 to 4 new incident microhemorrhage(s) AND microhemorrhages are asymptomatic (no clinical symptoms)
- Patient has had 5 to 9 new incident microhemorrhages AND microhemorrhages are asymptomatic (no clinical symptoms) AND the microhemorrhages have been stabilized
- Patient has had 1 to 9 new incident microhemorrhages AND microhemorrhages resulted in mild, moderate, or severe clinical symptoms AND the microhemorrhages have been stabilized

AND

5 - ONE of the following (ARIA-H, superficial siderosis):

- Patient has had no new incident areas of superficial siderosis
- Patient has had 1 new incident area of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms)
- Patient has had 2 new incident areas of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms) AND the superficial siderosis has been stabilized
- Patient has had 1 to 2 new incident areas of superficial siderosis AND superficial siderosis resulted in mild, moderate, or severe clinical symptoms AND the superficial siderosis has been stabilized

AND

6 - ONE of the following [ARIA-E (amyloid related imaging abnormalities - edema)]:

- Patient has had no new ARIA-E

- Patient has mild ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms)
- Patient has had moderate or severe ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms) AND the ARIA-E is stable
- Patient has had mild, moderate or severe ARIA-E on MRI AND ARIA-E resulted in mild, moderate, or severe clinical symptoms AND the ARIA-E is stable

AND

7 - One of the following:

7.1 Patient does NOT meet any of the following:

- Initiation of anticoagulation
- Development of active immune-mediated/autoimmune conditions (e.g., Crohn's disease, SLE, aplastic anemia, myasthenia gravis, meningitis/encephalitis)
- Initiation of immunomodulatory medications (e.g., cancer immunotherapies, rituximab, azathioprine)
- Development of other neurologic conditions (e.g., intracerebral bleeds, TBI, stroke)

OR

7.2 BOTH of the following:

- Patient does meet one of the above
- Prescriber documents clinical rationale for continued use of aducanumab (Aduhelm)

AND

8 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatric specialist

AND

9 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had greater than or equal to 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)

- If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity]
- If the patient has had greater than or equal to 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied

2 . Background

Clinical Practice Guidelines

Appendix

ARIA - H (Microhemorrhages)

		New Incident Microhemorrhages		
		Radiographic Severity		
		Mild (1 to 4)	Moderate (5 to 9)	Severe (≥10)
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		Stop Permanently
	Moderate			
	Severe			
	Serious	Stop Permanently		

ARIA - H (Superficial Siderosis)

		New Incident Areas of Superficial Siderosis (Central Read)		
		Radiographic Severity		
		Mild (1)	Moderate (2)	Severe (≥3)
Clinical Sympto	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently

m Severity	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved	Stop Permanently
	Moderate		
	Severe		
	Serious	Stop Permanently	

ARIA - E

		ARIA-E Severity on MRI (Central Read)		
		Radiographic Severity		
		Mild	Moderate	Severe
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		
	Moderate			
	Severe			
	Serious	Stop Permanently		

3 . Revision History

Date	Notes
8/25/2022	C&S to match FFS 10.1.22 except removed duplicate and unnecess ary notes and removal of all Medicare sections.

Aemcolo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110301
Guideline Name	Aemcolo
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Aemcolo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of travelers' diarrhea

AND

2 - History of failure, contraindication, or intolerance to ONE of the following:

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Afinitor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110670
Guideline Name	Afinitor
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Neuroendocrine tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Neuroendocrine tumors of pancreatic origin
- Neuroendocrine tumors of gastrointestinal origin
- Neuroendocrine tumors of lung origin

- Neuroendocrine tumors of thymic origin

AND

2 - Disease is progressive

AND

3 - One of the following:

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Neuroendocrine Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal cell cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell cancer

AND

2 - One of the following:

2.1 Disease has relapsed

OR

2.2 BOTH of the following

- Medically or surgically unresectable tumor
- Diagnosis of Stage IV disease

AND

3 - One of the following:

3.1 Patient with non-clear cell histology

OR

3.2 Both of the following:

3.2.1 Patient with predominantly clear cell histology

AND

3.2.2 History of failure, contraindication, or intolerance to at least one prior systemic therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib), Opdivo (nivolumab), Cabometyx (cabozantinib)]

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal cell cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is not a candidate for curative surgical resection

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Waldenströms macroglobulinemia
- Lymphoplasmacytic lymphoma

AND

2 - One of the following:

- Disease is non-responsive to primary treatment
- Disease is progressive
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Disease is recurrent

OR

2.2 Disease is metastatic

AND

3 - One of the following:

3.1 Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]

OR

3.2 BOTH of the following:

- Disease is hormone receptor negative (HR-)
- Disease has clinical characteristics that predict a HR+ tumor

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - One of the following:

5.1 Patient is a postmenopausal woman

OR

5.2 BOTH of the following:

- Patient is a premenopausal woman
- Patient is being treated with ovarian ablation/suppression

OR

5.3 Patient is male

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Used in combination with Aromasin (exemestane)

AND

6.1.2 One of the following:

6.1.2.1 Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy

OR

6.1.2.2 Patient was treated with tamoxifen at any time

OR

6.2 Used in combination with ONE of the following:

- Fulvestrant

- Tamoxifen

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of classical Hodgkin lymphoma

AND

2 - ONE of the following:

- Disease is refractory
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Hodgkin Lymphoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PEComa (perivascular epitheliod cell tumor)

OR

2 - Diagnosis of recurrent angiomyolipoma

OR

3 - Diagnosis of lymphangioleiomyomatosis

OR

4 - All of the following:

4.1 Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

4.2 Disease has progressed after single agent therapy with ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

AND

4.3 Used in combination with ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of thymic carcinoma
- Diagnosis of thymoma

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to at least one prior first-line chemotherapy regimen

OR

2.2 Patient has extrathoracic metastatic disease

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is recurrent or progressive

AND

3 - Surgery and/or radiation is not possible

AND

4 - Used in combination with bevacizumab (e.g., Avastin, Myasi)

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with letrozole

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberous sclerosis complex associated partial-onset seizures

AND

2 - Used as adjunctive therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Afinitor therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Afrezza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64348
Guideline Name	Afrezza
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Afrezza	
Diagnosis	Type 1 or Type 2 diabetes mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Patient is unable to self-inject medications (e.g. Humalog, Lantus, Levemir) due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Forced Expiratory Volume (FEV1) within the last 60 days is greater than or equal to 70% of expected normal as determined by the physician

AND

4 - Afrezza will not be approved in patients with ONE of the following:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months)
- With chronic lung disease (e.g. asthma, chronic obstructive pulmonary disease)

Product Name: Afrezza	
Diagnosis	Type 1 or Type 2 diabetes mellitus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in Forced Expiratory Volume (FEV1)

AND

2 - Patient continues to be unable to self-inject short-acting insulin due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Patient continues to not smoke cigarettes

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Airsupra (albuterol-budesonide)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134157
Guideline Name	Airsupra (albuterol-budesonide)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Airsupra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - Patient is 18 years of age or older

AND

3 - Trial and failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Brand Symbicort

AND

4 - Trial, failure, contraindication, or intolerance to BOTH of the following:

- Generic albuterol inhaler
- A preferred inhaled corticosteroid (e.g., Pulmicort, Brand Flovent, Asmanex)

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with Airsupra instead of taking individual products in combination (i.e., albuterol inhaler and Pulmicort)

Product Name: Airsupra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

2 . Revision History

Date	Notes

10/3/2023	New guideline.

Aldurazyme

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-63402
Guideline Name	Aldurazyme
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Aldurazyme	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I)

OR

1.2 Both the following:

1.2.1 Confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I)

AND

1.2.2 Have moderate to severe symptoms

2 . Revision History

Date	Notes
3/15/2020	C&S Implementation

Alinia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-78348
Guideline Name	Alinia
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Giardia lamblia
Approval Length	3 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giardiasis

AND

2 - History of failure, contraindication, or intolerance to metronidazole

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Cryptosporidium parvum
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cryptosporidiosis

2 . Revision History

Date	Notes
12/15/2020	Added generic tablet GPI

Alkeran

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-81445
Guideline Name	Alkeran
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Brand Alkeran tabs, generic melphalan tabs	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of palliative treatment of multiple myeloma

AND

2 - If the request is for generic melphalan, there is a reason or special circumstance the patient cannot use brand Alkeran

Product Name: Brand Alkeran tabs, generic melphalan tabs	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of palliative treatment of nonresectable epithelial ovarian

AND

2 - If the request is for generic melphalan, there is a reason or special circumstance the patient cannot use brand Alkeran

Product Name: Brand Alkeran tabs, generic melphalan tabs	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The use for Alkeran is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

AND

2 - If the request is for generic melphalan, there is a reason or special circumstance the patient cannot use brand Alkeran

Product Name: Brand Alkeran tabs, generic melphalan tabs	
Diagnosis	Multiple Myeloma, Ovarian Cancer, NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - There is documentation of positive clinical response to Alkeran therapy

2 . Revision History

Date	Notes
2/23/2021	New policy specific to Arizona.

Alpha Interferons

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110832
Guideline Name	Alpha Interferons
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Intron A	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of hairy cell leukemia

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of condylomata acuminata (genital or perianal)

OR

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma

OR

4 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of leptomeningeal metastases

OR

5 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of meningiomas

OR

6 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of kidney cancer

OR

7 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting treatment of myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or primary myelofibrosis (PM)

OR

8 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of follicular lymphoma

OR

9 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of adult T-cell leukemia, lymphoma

OR

10 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of mycosis fungoides, Sézary syndrome

OR

11 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of desmoid tumors/aggressive fibromatosis

OR

12 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of giant cell tumor of the bone

OR

13 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of malignant melanoma

Product Name: Alferon N	
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting

treatment of refractory or recurring external condylomata acuminata (genital or venereal warts) due to human papillomavirus (HPV) infection

2 . Revision History

Date	Notes
8/8/2022	C&S to match AZM 10.1.22

Alzheimer's Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-98067
Guideline Name	Alzheimer's Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Aricept, generic donepezil, Brand Namenda/Namenda XR, generic memantine/memantine XR, Brand Razadyne, generic galantamine hydrobromide, Brand Razadyne ER, generic galantamine ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of dementia of the Alzheimer’s type	

Product Name: Brand Exelon, generic rivastigmine	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dementia of the Alzheimer's type

OR

2 - Diagnosis of dementia associated with Parkinson's disease

Product Name: Adlarity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dementia of the Alzheimer's type

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to ALL of the following preferred drugs* (verified via paid pharmacy claims):

- generic donepezil
- generic galantamine IR/ER
- generic memantine
- generic oral rivastigmine

OR

2.2 Both of the following:

2.2.1 History of failure, contraindication, or intolerance to generic rivastigmine patch* (verified via paid pharmacy claims)

AND **2.2.2** Patient is unable to swallow oral formulations or has documented swallowing difficulties	
Notes	*PA may be required.

2 . Revision History

Date	Notes
8/8/2022	C&S to match AZM 10.1.22

Amondys 45

Prior Authorization Guideline

Guideline ID	GL-89417
Guideline Name	Amondys 45
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Amondys 45	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD) by, or in consultation with, a neurologist with expertise in the diagnosis of DMD

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 45 skipping

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Time (6MWT) greater than or equal to 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Amondys 45 therapy

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3.2.2 ONE of the following:

3.2.2.1 Patient has achieved a score of greater than 17 on the North Star Ambulatory Assessment (NSAA)

OR

3.2.2.2 Patient has achieved a time to rise from the floor (Gower's test) of less than 7 seconds

AND

4 - Amondys 45 is prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD

AND

5 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

6 - Amondys 45 is not used concomitantly with other exon skipping therapies for DMD

Product Name: Amondys 45	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Amondys 45 is prescribed by, or in consultation with, a neurologist with expertise in the treatment of Duchenne muscular dystrophy (DMD)

AND

2 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

4 - Amondys 45 is not used concomitantly with other exon skipping therapies for DMD

2 . Revision History

Date	Notes
7/9/2021	New policy specific to Arizona

Ampyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82532
Guideline Name	Ampyra
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2021

1 . Criteria

Product Name: Brand Ampyra, generic dalfampridine ER	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - Physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test)

Product Name: Brand Ampyra, generic dalfampridine ER	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Physician confirmation that the patient's walking improved with Ampyra therapy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP - eff 7.1

Anthelmintics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110302
Guideline Name	Anthelmintics
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Albenza, generic albendazole	
Diagnosis	See Note section*
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Enterobius vermicularis (pinworm)

OR

2 - Diagnosis of Hydatid Disease [Echinococcosis (Tapeworm)]

OR **3** - Diagnosis of Ancylostoma/Necatoriasis (Hookworm) **OR** **4** - Diagnosis of Ascariasis (Roundworm) **OR** **5** - Diagnosis of Mansonella perstans (Filariasis) **OR** **6** - Diagnosis of Toxocariasis (Roundworm) **OR** **7** - Diagnosis of Trichinellosis **OR** **8** - Diagnosis of Trichuriasis (Whipworm) **OR** **9** - Diagnosis of Capillariasis	
Notes	* Enterobius vermicularis (pinworm), Hydatid Disease [Echinococcosis (Tapeworm)] Ancylostoma/Necatoriasis (Hookworm), Ascariasis (Roundworm), Mansonella perstans (Filariasis), Toxocariasis (Roundworm), Trichinellosis, Trichuriasis (Whipworm), Capillariasis

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Neurocysticercosis
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurocysticercosis

Product Name: Brand Stromectol, generic ivermectin	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of intestinal strongyloidiasis due to the nematode parasite Strongyloides stercoralis

OR

2 - Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Anticonvulsants

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136578
Guideline Name	Anticonvulsants
Formulary	• Medicaid - Community & State Arizona • Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Aptiom, Briviact tabs/oral soln, generic lacosamide tabs/oral soln, Brand Vimpat tabs/oral soln, Xcopri	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.1.3 One of the following:

1.1.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.1.3.2 Both of the following:

- Documentation of failure of preferred formulary alternatives due to intolerable side effects
- Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

AND

1.1.4 Trial and failure, contraindication, or intolerance to generic lacosamide (APPLIES TO BRAND VIMPAT ONLY)

OR **1.2** For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Motpoly XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 Patient weighs at least 50 kg (kilograms)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Fycompa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of partial-onset or primary generalized tonic-clonic seizures

AND

1.1.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.1.3 ONE of the following:

1.1.3.1 BOTH of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.1.3.2 BOTH of the following:

- Documentation of failure of preferred formulary alternatives due to intolerable side effects

- Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Epidiolex	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome or tuberous sclerosis complex

OR

1.2 ALL of the following:

1.2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

1.2.2 History of greater than or equal to 8 week trial, contraindication, or intolerance of at least TWO of the following (any release formulation qualifies):

- Banzel (rufinamide)*
- Clobazam*
- Divalproex*
- Felbamate*
- Lamotrigine*
- Topiramate*
- Valproic acid*

AND

1.2.3 ONE of the following:

1.2.3.1 BOTH of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.2.3.2 BOTH of the following:

- Documentation of failure of preferred formulary alternatives due to intolerable side effects
- Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.3 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Onfi, generic clobazam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

OR

1.2 BOTH of the following:

- Diagnosis of Dravet syndrome
- Patient is currently taking Diacomit

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Brand Banzel, generic rufinamide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of seizures associated with Lennox-Gastaut syndrome

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Brand Gabitril, generic tiagabine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Sympazan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

1.1.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

1.1.3 History of greater than or equal to 8 week trial, contraindication, or intolerance of at least TWO of the following (any release formulation qualifies):

- Divalproex*
- Lamotrigine*
- Topiramate*
- Valproic acid*
- Felbamate*
- Banzel*

AND

1.1.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.2 ALL of the following:

1.2.1 Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

AND

1.2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

1.2.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.2.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.3 ALL of the following:

1.3.1 Diagnosis of Dravet syndrome

AND

1.3.2 Patient is currently taking Diacomit

AND

1.3.3 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.4 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Sabril powd pack, generic vigabatrin powd pack, Vigadrone powd pack	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of infantile spasms

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Sabril tabs, generic vigabatrin tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of complex partial seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Diacomit	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Dravet syndrome and currently taking clobazam

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Fintepla	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome

AND

1.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies):

- Divalproex (e.g., generic Depakote)
- Levetiracetam (e.g., generic Keppra)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

AND

1.3 ONE of the following:

1.3.1 BOTH of the following:

1.3.1.1 Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives

AND

1.3.1.2 Lack of compliance as a reason for treatment failure has been ruled out

OR

1.3.2 BOTH of the following:

1.3.2.1 Documentation of failure of preferred formulary alternatives due to intolerable side effects

AND

1.3.2.2 Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2.2 History of greater than or equal to 8 week trial, contraindication, or intolerance of at least TWO of the following (any release formulation qualifies):

- Banzel (rufinamide)*
- Clobazam*
- Divalproex*
- Felbamate*
- Lamotrigine*

- Topiramate*
- Valproic Acid*

AND

2.3 ONE of the following:

2.3.1 BOTH of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
- Lack of compliance as a reason for treatment failure has been ruled out

OR

2.3.2 BOTH of the following:

- Documentation of failure of preferred formulary alternatives due to intolerable side effects
- Lack of compliance as a reason for treatment failure has been ruled out

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

2 . Revision History

Date	Notes
11/20/2023	Updated verbiage regarding T/F of preferred formulary alternatives cr iteria.

Antidepressants

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134563
Guideline Name	Antidepressants
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/18/2023

1 . Criteria

Product Name: citalopram oral soln, fluoxetine soln, generic sertraline oral soln	
Diagnosis	Requests for Patients greater than 12 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is unable to swallow the oral tablet/capsule	
Notes	For group code ACUAZPH, antidepressant medications for patients with co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behavioral health conditions include, but are not limited to: anxiety, depression, obsessive-compulsive disorder, and panic disorder.

Product Name: generic mirtazapine, generic mirtazapine ODT, trazodone, generic citalopram tabs, citalopram oral soln, generic escitalopram, generic fluoxetine caps, fluoxetine soln, fluvoxamine IR, generic paroxetine IR tabs, generic sertraline tabs/oral soln, generic duloxetine 20 mg and 30 mg and 60 mg, venlafaxine tabs, generic venlafaxine ER caps, amitriptyline, amoxapine, generic clomipramine, generic desipramine, doxepin caps/conc, imipramine, generic nortriptyline, nortriptyline soln, protriptyline, trimipramine, bupropion tabs, generic bupropion ER (SR), generic bupropion ER (XL) 150 mg and 300 mg	
Diagnosis	PREFERRED DRUG Requests for patient 6 years of age or younger
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e., other medications or behavioral modification attempted) **AND** **2** - The physician attests that the requested medication is medically necessary (Document rationale for use)	
Notes	For group code ACUAZPH, antidepressant medications for patients wi th co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behav ioral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Brand Remeron, Brand Remeron Soltab, Marplan, Brand Nardil, generic phenelzine, Emsam, generic tranylcypromine, Brand Parnate, nefazodone, Brand Viibryd, Trintellix, Brand Celexa, Citalopram caps, Brand Lexapro, Brand Prozac, fluoxetine tabs, fluvoxamine ER, Brand Paxil, generic paroxetine ER, Brand Paxil CR, Brand Zoloft, Sertraline caps, paroxetine caps, generic paroxetine susp, Brand Pristiq, generic desvenlafaxine ER, Desvenlafaxine ER, Brand Cymbalta, duloxetine 40 mg, Fetzima Titration, Fetzima, Brand Effexor XR, venlafaxine ER tabs, Brand Anafranil, Brand Norpramin, Brand Pamelor, Brand Wellbutrin SR, Brand Wellbutrin XL, bupropion ER (XL) 450 mg, Forfivo XL, Aplenzin, Pexeva, Drizalma Sprinkle, generic vilazodone, Auvelity	
Diagnosis	Non-Preferred Drugs
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e., other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary (Document rationale for use)

AND

3 - Patient has a history of failure, contraindication, or intolerance to at least 3 of the following preferred alternatives*:

- Bupropion (Generic Wellbutrin)
- Bupropion SR (Generic Wellbutrin SR)
- Bupropion XL (Generic Wellbutrin XL) 150 mg and 300 mg
- Citalopram (Generic Celexa)
- Duloxetine 20mg, 30mg, or 60 mg capsules
- Escitalopram Tablets (Generic Lexapro)
- Esketamine (Spravato)
- Fluoxetine Capsules (Generic Prozac)
- Fluoxetine Solution (Generic Prozac)
- Fluvoxamine Tablets (Generic Luvox)
- Mirtazapine (Generic Remeron)
- Paroxetine tablets (Generic Paxil)
- Sertraline tablets (Generic Zoloft)
- Trazodone (Generic Desyrel)
- Venlafaxine (Generic Effexor)
- Venlafaxine ER Capsules (Generic Effexor ER)

Notes	For group code ACUAZPH, antidepressant medications for patients wi th co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behav ioral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder. *Drug may require PA.

Product Name: venlafaxine besylate ER

Diagnosis	Non-Preferred Drugs
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e., other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary (Document rationale for use)

AND

3 - Patient has history of failure or intolerance to preferred generic venlafaxine or venlafaxine ER capsules

AND

4 - Patient has a history of failure, contraindication, or intolerance to at least 2 of the following preferred alternatives*:

- Bupropion (Generic Wellbutrin)
- Bupropion SR (Generic Wellbutrin SR)
- Bupropion XL (Generic Wellbutrin XL) 150 mg and 300 mg
- Citalopram (Generic Celexa)
- Duloxetine 20mg, 30mg, or 60 mg capsules
- Escitalopram Tablets (Generic Lexapro)
- Esketamine (Spravato)
- Fluoxetine Capsules (Generic Prozac)
- Fluoxetine Solution (Generic Prozac)
- Fluvoxamine Tablets (Generic Luvox)
- Mirtazapine (Generic Remeron)
- Paroxetine tablets (Generic Paxil)
- Sertraline tablets (Generic Zoloft)
- Trazodone (Generic Desyrel)

Notes	For group code ACUAZPH, antidepressant medications for patients wi th co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behav ioral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder. *Drug may require PA.

2 . Revision History

Date	Notes
10/18/2023	Moved Sertraline capsule and paroxetine suspension from preferred to non-preferred. Removed citalopram capsule GPI from preferred se ction. Updated product names of both preferred and non-preferred se ctions. Updated T/F list to specify sertraline tablets are the preferred prerequisite.

Antiemetics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-63416
Guideline Name	Antiemetics
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Nausea and vomiting associated with cancer chemotherapy
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prevention or treatment of nausea and vomiting associated with cancer chemotherapy	

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Nausea and vomiting associated with radiotherapy
Approval Length	3 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Prevention or treatment of nausea and vomiting associated with radiotherapy (total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen)

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Postoperative nausea and/or vomiting
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Prevention of postoperative nausea and/or vomiting (administration prior to induction of anesthesia)

2 . Revision History

Date	Notes
3/16/2020	C&S Implementation

Antiglaucoma Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110375
Guideline Name	Antiglaucoma Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Zioptan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of elevated intraocular pressure due to ocular hypertension or open angle glaucoma	

2 . Revision History

Date	Notes

8/4/2022	C&S to match AZM as of 10.1.22

Antipsoriatic Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110352
Guideline Name	Antipsoriatic Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Dovonex cream, generic calcipotriene cream, Brand Calcitrene ointment, generic calcipotriene ointment, Brand Vectical, generic calcitriol ointment	
Diagnosis	Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of psoriasis

AND

2 - History of failure, contraindication, or intolerance to TWO medium to Very high potency corticosteroid topical treatments (see Table 1 in Background section)

2 . Background

Benefit/Coverage/Program Information

Table 1. Relative Potency of Selected Topical Corticosteroid Products

Drug	Dosage Form	Strength
Super High Potency		
Augmented betamethasone dipropionate (Diprolene)	Gel, Ointment	0.05%
Clobetasol propionate (Temovate, Temovate E)	Cream, Solution	0.05%
Halobetasol propionate (Ultravate)	Cream	0.05%
High Potency		
Augmented betamethasone dipropionate (Diprolene, Diprolene AF)	Cream, Lotion	0.05%
Betamethasone dipropionate	Lotion, Ointment	0.05%
Fluocinonide (Lidex, Lidex E)	Cream, Solution	0.05%
Triamcinolone acetonide (Kenalog)	Cream, Ointment	0.5%
Medium Potency		
Betamethasone valerate (Beta-Val)	Cream	0.1%
Fluocinolone acetonide (Synalar)	Cream, Ointment	0.025%
Fluticasone propionate (Cutivate)	Cream, Lotion	0.05%

	Ointment	0.005%
Hydrocortisone butyrate (Locoid)	Ointment, Solution	0.1%
Mometasone furoate (Elocon)	Cream, Ointment, Solution	0.1%
Prednicarbate (Dermatop)	Cream	0.1%
Triamcinolone acetonide (Kenalog)	Cream, Lotion, Ointment	0.1%
	Ointment	0.025%

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Antipsychotics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136055
Guideline Name	Antipsychotics
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Brand Abilify tabs, generic aripiprazole tabs, generic ziprasidone caps, Brand Geodon caps, Brand Latuda, lithium carbonate, generic lithium carbonate ER, Brand Lithobid, fluphenazine tabs/elix/oral conc, generic risperidone tabs/soln, Brand Risperdal tabs/soln, risperidone ODT, generic quetiapine, Brand Seroquel, chlorpromazine tabs, Brand Zyprexa, generic olanzapine, generic olanzapine ODT, Brand Zyprexa Zydis, generic lurasidone	
Diagnosis	Patients Under 6 Years Old
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been diagnosed per current DSM (Diagnostic and Statistical Manual of Mental Disorders) criteria with one of the following disorders:

- Bipolar Spectrum Disorder
- Schizophrenic Spectrum Disorder
- Tourette's or other tic disorder
- Autism Spectrum Disorder

AND

2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for antipsychotic medications

AND

3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for antipsychotic medications

AND

4 - The above documentation includes information on the expected outcomes and an evaluation of potential adverse events

AND

5 - The patient does not have a known hypersensitivity to the requested agent

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: haloperidol tabs/oral conc, loxapine, thioridazine, molindone, thiothixene, pimozide, fluphenazine tabs/elix/oral conc, trifluoperazine, perphenazine, chlorpromazine tabs	
Diagnosis	Patients Under 12 Years Old
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been diagnosed per current DSM (Diagnostic and Statistical Manual of Mental Disorders) criteria with one of the following disorders:

- Bipolar Spectrum Disorder
- Schizophrenic Spectrum Disorder
- Tourette's or other tic disorder
- Autism Spectrum Disorder

AND

2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for antipsychotic medications

AND

3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for antipsychotic medications

AND

4 - The above documentation includes information on the expected outcomes and an evaluation of potential adverse events

AND

5 - The patient does not have a known hypersensitivity to the requested agent

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behavioral health conditions include, but are not limited to: anxiety, depression, obsessive-compulsive disorder, and panic disorder.

Product Name: generic clozapine, Brand Clozaril, clozapine ODT, generic haloperidol decanoate, Brand Haldol Decanoate, fluphenazine decanoate, haloperidol lactate inj

Diagnosis	Patients Under 18 Years Old
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 The requested medication must be used for an FDA (Food and Drug Administration) approved indication

OR

1.1.2 The use of the drug is supported by information in ONE of the following appropriate compendia of literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type, and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential patient outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data, and pharmacoeconomic studies
- Other drug reference resources

AND

1.2 The patient meets the FDA minimum age limit or the prescriber attests they are aware of FDA labeling regarding the use of the antipsychotic medication and feels the treatment with the requested medication is medically necessary (document rationale for use)

OR

2 - The patient is currently on the requested medication	
Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behavioral health conditions include, but are not limited to: anxiety, depression, obsessive-compulsive disorder, and panic disorder.

Product Name: Abilify Asimtufii, Abilify Maintena	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

AND

2.1.2 Patient has established tolerability with aripiprazole

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (document rationale for use)	
Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Abilify Mycite	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient has ONE of the following:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder
- Autism
- Major depressive disorder
- Tourette's

OR

1.2 Submission of medical records or claims history documenting the patient is currently prescribed aripiprazole and tolerates the medication

AND

1.3 Submission of medical records or claims history documenting the patient's adherence to aripiprazole is less than 80 percent within the past 6 months (medication adherence percentage is defined as the number of pills absent in a given time period divided by the number of pills prescribed during that same time, multiplied by 100)

AND

1.4 ALL of the following strategies (if applicable to the patient) to improve patient adherence have been tried without success:

- Utilization of a pill box
- Utilization of a smart phone reminder (ex. alarm, application, or text reminder)
- Involving family members or friends to assist
- Coordinating timing of dose to coincide with dosing of another daily medication

AND

1.5 Submission of medical records or claims history documenting patient has experienced life-threatening or potentially life-threatening symptoms, or has experienced a severe worsening of symptoms leading to a hospitalization which was attributed to the lack of adherence to aripiprazole

AND

1.6 Prescriber acknowledges that Abilify MyCite has not been shown to improve patient adherence and attests that Abilify MyCite is medically necessary for the patient to maintain compliance, avoid life-threatening worsening of symptoms, and reduce healthcare resources utilized due to lack of adherence

AND

1.7 Prescriber agrees to track and document adherence of Abilify MyCite through software provided by the manufacturer

AND

1.8 The patient has a history of failure, contraindication, or intolerance or reason or special circumstance they cannot use TWO of the following (drug may require PA):

- Abilify Maintena
- Invega Sustenna
- Risperdal Consta
- Aristada

- Perseris

OR

2 - ONE of the following:

2.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behavioral health conditions include, but are not limited to: anxiety, depression, obsessive-compulsive disorder, and panic disorder.

Product Name: Abilify Mycite	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient is clinically stable on Abilify MyCite

AND

2 - Submission of medical records or claims history documenting that the use of Abilify MyCite has increased adherence to 80 percent or more

AND

3 - Prescriber attests that the patient requires the continued use of Abilify MyCite to remain adherent	
Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behavioral health conditions include, but are not limited to: anxiety, depression, obsessive-compulsive disorder, and panic disorder.

Product Name: Aristada, Aristada Initio	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

AND

2.1.2 Patient has established tolerability with oral aripiprazole

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA

(Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (document rationale for use)	
Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Invega Sustenna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

AND

2.1.2 Patient has established tolerability with oral paliperidone or oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA

(Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (document rationale for use)	
Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Invega Trinza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - Patient has been treated with Invega Sustenna for at least 4 months

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (document rationale for use)

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Invega Hafyera	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - Patient has been treated with Invega Sustenna or Invega Trinza for at least 6 months

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (document rationale for use)

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Lybalvi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of schizophrenia

AND

1.2 BOTH of the following:

1.2.1 Patient has a history of failure, contraindication, or intolerance to at least FOUR of the following:

- Aripiprazole oral (generic Abilify)
- Aripiprazole injectable formulations (Abilify Maintena, Aristada, Aristada Initio)
- Clozapine/clozapine ODT (orally disintegrating tablets)
- Lurasidone
- Paliperidone oral
- Paliperidone injectable formulations (e.g., Invega Trinza, Invega Sustenna, Invega Hafyera)
- Quetiapine
- Risperidone/risperidone ODT
- Risperidone injectable formulations (Perseris, Risperdal Consta)

AND

1.2.2 Failure to respond to generic olanzapine (Generic Zyprexa) given at maximum dosage

OR

2 - ALL of the following:

2.1 Diagnosis of bipolar I disorder

AND

2.2 History of failure, contraindication, or intolerance to ALL of the following preferred** alternatives:

- Lamotrigine
- Lithium
- Valproate

AND

2.3 History of failure, contraindication, or intolerance to THREE of the following preferred** alternatives:

- Aripiprazole
- Lurasidone

- Quetiapine
- Risperidone

OR

3 - ONE of the following:

3.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

3.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behavioral health conditions include, but are not limited to: anxiety, depression, obsessive-compulsive disorder, and panic disorder. *Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexual dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Perseris	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

AND

2.1.2 Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (document rationale for use)

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Risperdal Consta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

AND

2.1.2 Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (document rationale for use)

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Rykindo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - History of failure, contraindication, or intolerance to Risperdal Consta

AND

4 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Uzedy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - History of failure, contraindication, or intolerance to BOTH of the following:

- Perseris
- Risperdal Consta

AND

4 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through t he Regional Behavioral Health Authority (RBHA). Examples of behavi oral health conditions include, but are not limited to: anxiety, depressi on, obsessive-compulsive disorder, and panic disorder.

Product Name: Brand Abilify, aripiprazole oral soln, aripiprazole ODT, Brand Clozaril, generic ziprasidone caps, Brand Geodon caps, Brand Haldol Decanoate, generic paliperidone ER, Brand Invega, Fanapt, Fanapt Titration, Brand Latuda, loxapine, Brand Lithobid, fluphenazine tabs/inj, Brand Risperdal, generic risperidone soln, Brand Saphris, generic asenapine SL, Secuado, generic olanzapine/fluoxetine, Brand Symbyax, Brand Seroquel, generic quetiapine ER, Brand Seroquel XR, chlorpromazine tabs, perphenazine/amitriptyline, Versacloz, Brand Zyprexa, Brand Zyprexa Zydis, Zyprexa Relprevv, generic haloperidol lactate inj	
Diagnosis	Non-Preferred Drugs**
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 Patient has a history of failure, contraindication, or intolerance to at least FOUR of the following:

- Aripiprazole oral (generic Abilify)
- Aripiprazole injectable formulations (Abilify Maintena, Aristada, Aristada Initio)
- Clozapine/clozapine ODT
- Lurasidone
- Olanzapine/olanzapine ODT
- Paliperidone oral (does not apply to requests for paliperidone ER tablets)***
- Paliperidone injectable formulations (Invega Sustenna, Invega Trinza, Hafyera)
- Quetiapine
- Risperidone/risperidone ODT
- Risperidone injectable formulations (Perseris, Risperdal Consta)

OR

1.1.2 There are no preferred formulary alternatives for the requested drug

AND

1.2 If the request is for a multi-source brand medication (i.e., MSC O), ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 The brand is being requested because of an adverse reaction, allergy, or sensitivity to the generic, and the prescriber must attest to submitting the FDA (Food and Drug Administration) MedWatch Form for allergic reactions to the medications

AND

1.2.1.2 If there are generic product(s), the patient has tried at least three (if available)

OR

1.2.2 ONE of the following:

1.2.2.1 The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure)

OR

1.2.2.2 The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided)

OR

1.2.2.3 Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the patient (rationale must be provided)

AND

1.3 ONE of the following:

1.3.1 The requested drug must be used for an FDA-approved indication

OR

1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- FDA approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type, and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential patient outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data, and pharmacoeconomic studies
- Other drug reference resources

AND

1.4 ONE of the following:

1.4.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

1.4.2 The drug falls within dosing guidelines found in ONE of the following compendia of current literature:

- FDA approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type, and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential patient outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data, and pharmacoeconomic studies
- Other drug reference resources

AND

1.5 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program* **OR** **2** - The requested medication is a behavioral health medication and ONE of the following: **2.1** The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days) **OR** **2.2** The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge	
Notes	For group code ACUAZPH, antipsychotic medications for patients with co-existing behavioral health conditions should be provided through the Regional Behavioral Health Authority (RBHA). Examples of behavioral health conditions include, but are not limited to: anxiety, depression, obsessive-compulsive disorder, and panic disorder. *Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexual dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP ***If the request is for generic paliperidone ER tablets, please omit "paliperidone oral" as an alternative.

2 . Revision History

Date	Notes
11/7/2023	Added Rykindo (new NP) and Abilify Asimtufii (moving to Preferred).

Anxiolytics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127925
Guideline Name	Anxiolytics
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: buspirone, Brand Xanax tabs, Brand Xanax XR, generic alprazolam tabs, alprazolam ODT, generic alprazolam ER/XR, chlordiazepoxide, generic clorazepate dipotassium, Brand Tranxene T, Brand Valium tabs, generic diazepam tabs, diazepam conc, diazepam intensol, generic lorazepam, Brand Ativan, lorazepam conc, lorazepam intensol, oxazepam, generic clonazepam tabs, Brand Klonopin tabs, clonazepam ODT, alprazolam intensol, Loreev XR	
Diagnosis	Requests for patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e., other medications or behavioral modification attempted)	

AND

2 - The physician attests that the requested medication is medically necessary (document rationale for use)

Product Name: Loreev XR	
Diagnosis	Requests for Patients 6 years of age and older
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure, or contraindication to generic lorazepam

AND

2 - The physician attests that the requested medication is medically necessary (document rationale for use)

Product Name: buspirone, Brand Xanax tabs, Brand Xanax XR, generic alprazolam tabs, alprazolam ODT, generic alprazolam ER/XR, chlordiazepoxide, generic clorazepate dipotassium, Brand Tranxene T, Brand Valium tabs, generic diazepam tabs, diazepam conc, diazepam intensol, generic lorazepam, Brand Ativan, lorazepam conc, lorazepam intensol, oxazepam, generic clonazepam tabs, Brand Klonopin tabs, clonazepam ODT, alprazolam intensol, Loreev XR	
Diagnosis	Greater than 1 Anxiolytic in 30 days
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The medication is being used to adjust the dose of the drug

OR **2** - The medication will be used in place of the previously prescribed drug, and not in addition to it **OR** **3** - The medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it **OR** **4** - The physician attests they are aware of the multiple anxiolytics prescribed to the patient and feels treatment with both medications is medically necessary (document rationale for use)

2 . Revision History

Date	Notes
7/13/2023	Updated Indication for Greater than 1 Anxiolytic in 30 days to remove reject number and type.

Apomorphine products (Apokyn, Kynmobi)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110596
Guideline Name	Apomorphine products (Apokyn, Kynmobi)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Apokyn, generic apomorphine injection, Kynmobi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of Parkinson’s disease

AND

1.2 Medication will be used as intermittent treatment for OFF episodes

AND

1.3 Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

1.4 Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

1.5 History of failure, contraindication, or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

AND

2 - Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

Product Name: Brand Apokyn, generic apomorphine injection, Kynmobi	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Aquadeks

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110328
Guideline Name	Aquadeks
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Aquadeks	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis	

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Aralast NP

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110576
Guideline Name	Aralast NP
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Aralast NP	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has clinically evident emphysema

AND

2 - Patient has a diagnosis of severe congenital deficiency of Alpha1- proteinase inhibitor (alpha1 antitrypsin deficiency)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Arcalyst

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110593
Guideline Name	Arcalyst
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) [including Familial Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), etc]

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Arcalyst therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Arikayce

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110671
Guideline Name	Arikayce
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting respiratory cultures positive for MAC within the previous 6 months

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting the patient has been receiving a multidrug background regimen containing at least TWO of the following agents for a minimum of 6 consecutive months within the past 12 months (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

- Macrolide antibiotic* (e.g., azithromycin, clarithromycin)
- Ethambutol*
- Rifamycin antibiotic* (e.g., rifampin, rifabutin)

AND

4 - Patient will continue to receive a multidrug background regimen

AND

5 - Documentation that the patient has not achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

AND

6 - In vitro susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 micrograms per milliliter (mcg/mL)

AND

7 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Notes	*Drug may require PA)

Product Name: Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Documentation that the patient has achieved negative respiratory cultures

OR

1.2 ALL of the following:

1.2.1 Patient has not achieved negative respiratory cultures while on Arikayce

AND

1.2.2 Physician attestation that patient has demonstrated clinical benefit while on Arikayce

AND

1.2.3 In vitro susceptibility testing of most recent (within 6 months) positive culture with available susceptibility testing documents that the Mycobacterium avium complex (MAC) isolate is susceptible to amikacin with an minimum inhibitory concentration (MIC) of less than 64 micrograms per milliliter (mcg/mL)

AND

1.2.4 Patient has NOT received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

AND **2** - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting that the patient continues to receive a multidrug background regimen containing at least TWO of the following agents (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration): • Macrolide antibiotic* (e.g., azithromycin, clarithromycin) • Ethambutol* • Rifamycin antibiotic* (e.g., rifampin, rifabutin) **AND** **3** - Prescribed by or in consultation with one of the following: • Infectious disease specialist • Pulmonologist

Notes	*Drug may require PA

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Atorvaliq (atorvastatin oral suspension)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125935
Guideline Name	Atorvaliq (atorvastatin oral suspension)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Atorvaliq	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is less than 10 years of age

AND

1.2 Prescribed by or in consultation with a cardiologist

OR

2 - BOTH of the following:

2.1 Medication is being used for ONE of the following:

2.1.1 To reduce the risk of ONE of the following:

2.1.1.1 Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD

OR

2.1.1.2 MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD

OR

2.1.1.3 Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD

OR

2.1.2 As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in ONE of the following:

- Adults with primary hyperlipidemia
- Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)

OR

2.1.3 As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH)

OR

2.1.4 As an adjunct to diet for the treatment of adults with ONE of the following:

- Primary dysbetalipoproteinemia
- Hypertriglyceridemia

AND

2.2 ONE of the following:

2.2.1 Trial and failure, contraindication, or intolerance to generic atorvastatin tablets (verified via paid pharmacy claims or submitted chart notes)

OR

2.2.2 Patient is unable to swallow oral tablets

2 . Revision History

Date	Notes
5/22/2023	Updated all criteria to allow patients under 10 years old with cardiolo gist prescriber to bypass PA criteria.

Austedo (deutetrabenazine)

Prior Authorization Guideline

Guideline ID	GL-132791
Guideline Name	Austedo (deutetrabenazine)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Austedo Patient Titration Kit, Austedo, Austedo XR, Austedo XR Patient Titration Kit	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia (TD) secondary to treatment with a centrally acting dopamine receptor blocking agent (DRBA)

AND

2 - Prescribed by or in consultation with a psychiatrist or neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Patient has an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of the AIMS items 1 through 9

AND

5 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

6 - Dose does not exceed 48 mg (milligrams) per day

AND

7 - If the request is for Austedo XR, the patient had ONE of the following:

- Trial and failure of Austedo
- Intolerance to Austedo

Product Name: Austedo Patient Titration Kit, Austedo, Austedo XR, Austedo XR Patient Titration Kit	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline score of any one of the Abnormal Involuntary Movement Scale (AIMS) items 1 through 9

AND

2 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

3 - Dose does not exceed 48 mg per day

Product Name: Austedo Patient Titration Kit, Austedo, Austedo XR, Austedo XR Patient Titration Kit	
Diagnosis	Chorea Associated with Huntington Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea associated with Huntington’s Disease

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Targeted mutation analysis demonstrates a cytosine-adenine-guanine (CAG) trinucleotide expansion of at least 36 repeats in the huntingtin (HTT) gene

AND

5 - Patient has a Unified Huntington Disease Rating Scale (UHDRS) score ranging from 1 to 4 on any one of UHDRS chorea items 1 through 7

AND

6 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

7 - Dose does not exceed 48 mg per day

AND

8 - If the request is for Austedo XR, the patient had ONE of the following:

- Trial and failure of Austedo
- Intolerance to Austedo

Product Name: Austedo Patient Titration Kit, Austedo, Austedo XR, Austedo XR Patient Titration Kit	
Diagnosis	Chorea Associated with Huntington Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline score of any one of the Unified Huntington Disease Rating Scale (UHDRS) chorea items 1 through 7

AND

2 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

3 - Dose does not exceed 48 mg per day

2 . Revision History

Date	Notes
9/11/2023	Added GPI for Austedo XR titration pack, cleaned up criteria.

Azole Antifungals

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134135
Guideline Name	Azole Antifungals
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Systemic Fungal Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following

1.1 Diagnosis of ONE of the following:

- Blastomycosis
- Histoplasmosis

- Aspergillosis

OR

1.2 Both of the following:

1.2.1 Diagnosis of coccidioidomycosis

AND

1.2.2 Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fingernail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

AND

2 - Patient has a history of at least a 6-week trial resulting in therapeutic failure, contraindication, intolerance, or resistance to Terbinafine as evidenced by submission of medical records or claims history

Product Name: Brand Sporanox capsules, generic itraconazole capsules

Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Three months have elapsed since completion of initial therapy for fingernail onychomycosis

AND

1.2 Documentation of positive clinical response to therapy

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of toenail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

AND

2 - Patient has a history of at least a 12-week trial resulting in therapeutic failure, contraindication, intolerance, or resistance to Terbinafine as evidenced by submission of medical records or claims history

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Nine months have elapsed since completion of initial therapy for toenail onychomycosis

AND

1.2 Documentation of positive clinical response to therapy

Product Name: Brand Sporanox Oral Solution, generic itraconazole oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Oropharyngeal candidiasis
- Esophageal candidiasis

Product Name: Brand Vfend tablets, generic voriconazole tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

1.2 ALL of the following:

- Diagnosis of Candidemia
- Patient is non-neutropenic
- Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.3 Both of the following:

1.3.1 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

AND

1.3.2 Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.4 Diagnosis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

1.5 Diagnosis of Fusarium spp. infection including Fusarium solani

OR

1.6 Diagnosis of Exserohilum species infection

Product Name: Brand Vfend Powder for Oral Suspension, generic voriconazole powder for oral suspension	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

1.1.2 ALL of the following:

- Diagnosis of Candidemia
- Patient is non-neutropenic
- Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.1.3 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

OR

1.1.4 Diagnosis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

1.1.5 Diagnosis of Fusarium spp. infection including Fusarium solani

OR

1.1.6 Diagnosis of Exserohilum species infection

AND

1.2 Physician has provided rationale for the patient needing to use voriconazole oral suspension instead of voriconazole tablets

Product Name: Brand Noxafil tablets, generic posaconazole tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

1.2 One of the following conditions:

1.2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

1.2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name: Noxafil Suspension, Noxafil delayed release suspension packets	
Diagnosis	Prophylaxis of Aspergillus or Candida Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

1.2 One of the following conditions:

1.2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

1.2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name: Noxafil Suspension	
Diagnosis	Oropharyngeal Candidiasis (OPC)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of oropharyngeal candidiasis (OPC)

AND

1.2 The patient has a history of failure, contraindication, intolerance, or resistance to TWO of the following as evidenced by submission of medical records or claims history:

- Fluconazole* (generic Diflucan)
- Itraconazole* (generic Sporanox)
- Clotrimazole Lozenges*

Notes	*Drug may require PA

Product Name: Cresemba	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of invasive aspergillosis

AND

1.1.2 Patient has a history of failure, contraindication, intolerance, or resistance to voriconazole* (generic Vfend) as evidenced by submission of medical records or claims history

OR

1.2 Diagnosis of invasive mucormycosis

Notes	*Drug may require PA

Product Name: Tolsura	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of ONE of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

1.2 Patient has a history of failure, contraindication, intolerance, or resistance to itraconazole* capsules (generic Sporanox) as evidenced by submission of medical records or claims history

Notes	*Drug may require PA

Product Name: Brand Sporanox capsules, generic itraconazole capsules, Brand Sporanox oral solution, generic itraconazole oral solution, Brand Vfend tablets, generic voriconazole tablets, Brand Vfend powder for oral suspension, generic voriconazole powder for oral suspension, Brand Noxafil tablets, generic posaconazole tablets, Noxafil oral suspension, Noxafil delayed release suspension packets, Cresemba, Tolsura	
Diagnosis	All Other Diagnoses
Guideline Type	Prior Authorization

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

2 - The medication is being prescribed by or in consultation with an infectious disease specialist

Notes	*Authorization duration based on provider recommended treatment du rations, not to exceed 12 months

2 . Revision History

Date	Notes
10/4/2023	Added new GPI for Cresemba

Baxdela

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110329
Guideline Name	Baxdela
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Baxdela	
Diagnosis	Community-Acquired Bacterial Pneumonia
Approval Length	10 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

3.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics or antibiotic regimens:

- Amoxicillin**
- A macrolide**
- Doxycycline**
- A fluoroquinolone**
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Notes	*Note: Authorization will be issued for up to 10 days. **Drug may require PA

Product Name: Baxdela	
Diagnosis	Acute Bacterial Skin and Skin Structure Infections
Approval Length	14 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 One of the following diagnoses:

3.1.1 Both of the following

3.1.1.1 Acute bacterial skin and skin structure infections

AND

3.1.1.2 Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

3.1.2 Both of the following:

3.1.2.1 Empirical treatment of patients with acute bacterial skin and skin structure infections

AND

3.1.2.2 Presence of MRSA infection is likely

AND

3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

3.3 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)**
- A tetracycline**
- Clindamycin**

OR

4 - All of the following:

4.1 Diagnosis of acute bacterial skin and skin structure infections

AND

4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

4.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics:

- A penicillin**
- A cephalosporin**
- A tetracycline**
- Sulfamethoxazole-trimethoprim (SMZ-TMP)**
- Clindamycin**

Notes	*Note: Authorization will be issued for up to 14 days. **Drug may require PA

Product Name: Baxdela	
Diagnosis	Off-Label Uses*
Guideline Type	Prior Authorization

Approval Criteria **1** - For continuation of therapy upon hospital discharge **OR** **2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication	
Notes	*Note: Authorization duration based on provider recommended treatment durations, up to 6 months.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Belbuca, Butrans

Prior Authorization Guideline

Guideline ID	GL-118256
Guideline Name	Belbuca, Butrans
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Belbuca, Brand Butrans, generic buprenorphine patches*	
Diagnosis	Cancer/Hospice/End of Life related pain
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for cancer, hospice, or end of life related pain

AND

2 - If the request is for Belbuca or generic buprenorphine patches, BOTH of the following:

2.1 Prescriber attests the information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

AND

2.2 The patient has a history of failure, contraindication, or intolerance to BRAND Butrans

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12 month authorization should be entered for brand buprenorphine patches.

Product Name: Belbuca, Brand Butrans, generic buprenorphine patches	
Diagnosis	Cancer/Hospice/End of Life related pain
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for cancer, hospice, or end of life related pain (Document diagnosis and date of diagnosis)

AND

2 - If the request is for Belbuca or generic buprenorphine patches ONLY: Prescriber attests

the information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

Product Name: Belbuca, Brand Butrans, generic buprenorphine patches*	
Diagnosis	Non-cancer pain/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

1.1 The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

AND

1.2 Treatment goals are defined, including estimated duration of treatment

AND

1.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

AND

1.4 Patient has been screened for substance abuse/opioid dependence

AND

1.5 If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the

prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

1.6 Pain is moderate to severe and expected to persist for an extended period of time

AND

1.7 Pain is chronic

AND

1.8 Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)

AND

1.9 Pain management is required around the clock with a long-acting opioid

AND

2 - The patient has a history of failure, contraindication, or intolerance to a trial of tramadol IR (immediate release), unless the patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time (Drug may require PA)

AND

3 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following must be met:

3.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin (Neurontin) or pregabalin (Lyrica) titrated to a therapeutic dose (document date of trial)

AND

3.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial)

AND

4 - If the request is for Belbuca or generic Butrans, the patient has a history of failure, contraindication or intolerance to BRAND Butrans

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for brand buprenorphine patches.

Product Name: Belbuca, Brand Butrans, generic buprenorphine patches*	
Diagnosis	Non-cancer pain/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (document rationale)

AND

3 - Prescriber attests to ALL of the following:

3.1 The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

AND

3.2 Treatment goals are defined, including estimated duration of treatment

AND

3.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

AND

3.4 Patient has been screened for substance abuse/opioid dependence

AND

3.5 If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

3.6 Pain is moderate to severe and expected to persist for an extended period of time

AND

3.7 Pain is chronic

AND

3.8 Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)

AND

3.9 Pain management is required around the clock with a long-acting opioid

AND

4 - If the request is for Belbuca or generic Butrans, the patient has a history of failure, contraindication, or intolerance to BRAND Butrans

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for brand buprenorphine patches.

Product Name: Belbuca, Brand Butrans, generic buprenorphine patches	
Guideline Type	Quantity Limit

Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the FDA (Food and Drug Administration) maximum dose per day, where an FDA maximum dose per day exists	
Notes	Approval durations: 12 months for cancer pain/hospice/end of life related pain; 6 months for non-cancer pain/non-hospice/non-end of life related pain

2 . Revision History

Date	Notes
12/12/2022	Updated prerequisite options for neuropathic/nerve pain in Non-cancer pain/Non-hospice/Non-end of life care pain initial auth section.

Benefit Determination Mifeprex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123261
Guideline Name	Benefit Determination Mifeprex
Formulary	• Medicaid - Community & State Arizona • Medicaid - Community & State Florida MMA • Medicaid - Community & State Indiana • Medicaid - Community & State Kansas • Medicaid - Community & State Louisiana • Medicaid - Community & State Michigan • Medicaid - Community & State Mississippi • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Texas • Medicaid - Community & State Virginia Medicaid - Community & State Nebraska

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Brand Mifeprex, generic mifepristone	
Approval Length	1 month(s)
Guideline Type	Benefit Determination

Approval Criteria

1 - Provider attests patient requires treatment for purposes identified in the Hyde amendment and any applicable state laws and regulations

AND

2 - Submission of all necessary state form(s) and/or certification document(s)

2 . Revision History

Date	Notes
3/15/2023	Added KS and changed GL type to " benefit determination

Benlysta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116037
Guideline Name	Benlysta
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic lupus erythematosus

AND

2 - Patient is 5 years of age or older

AND

3 - Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]

AND

4 - Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

5 - Patient does NOT have severe active central nervous system lupus

AND

6 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Product Name: Benlysta SQ	
Diagnosis	Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is 5 years of age or older

AND

3 - Patient is currently receiving standard immunosuppressive therapy for systemic lupus erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

4 - Patient does NOT have severe active central nervous system lupus

AND

5 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Product Name: Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus, Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Benlysta therapy

AND

2 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

2 . Revision History

Date	Notes
10/24/2022	Updated age requirement.

Benznidazole

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64355
Guideline Name	Benznidazole
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Benznidazole	
Diagnosis	Chagas disease (American trypanosomiasis)
Approval Length	60 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Chagas disease (American trypanosomiasis) due to Trypanosoma cruzi	

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Biltricide

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64356
Guideline Name	Biltricide
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Biltricide, generic praziquantel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Infections due to schistosoma

OR

1.2 Infections due to the liver trematodes (flukes), Clonorchis sinensis/Opisthorchis viverrini (i.e., clonorchiasis or opisthorchiasis)

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Blood Glucose Monitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-112394
Guideline Name	Blood Glucose Monitors
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Non-preferred Blood Glucose Monitors*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is visually impaired	
Notes	*Please reference background table for list of Non-preferred Blood Glucose Monitors. *Approve Glucose Monitor at NDC Level.

2 . Background

Benefit/Coverage/Program Information

Non-preferred Blood Glucose Monitors

CONTOUR KIT NEXT LNK	EASY TOUCH KIT MONITOR	EASYMAX V KIT SYSTEM
CONTOUR NXT KIT LINK 2.4	KROGER BGM KIT SYSTEM	EASYMAX NG KIT SYSTEM
CONTOUR KIT NEXT EZ	ELEMENT AUTO KIT SYSTEM	MEIJER BGM KIT ESSENTIA
CONTOUR KIT NEXT	SMARTEST KIT EJECT	MEIJER GLUCO KIT MONITOR
CONTOUR KIT MONITOR	SMARTEST KIT PROTEGE	MEIJER BGM KIT PREMIUM
RELION MICRO KIT	SMARTEST KIT PRONTO	FORA V30A KIT
RELION KIT MONITOR	SMARTEST KIT PERSONA	FORA TN'G KIT VOICE
BD LOGIC KIT MONITOR	GLUCOCOM KIT MONITOR	REFUAH PLUS KIT SYSTEM
BD LATITUDE KIT	RIGHTEST SYS KIT GM300	KROGER BGM KIT
BD LATITUDE KIT SYSTEM	RIGHTEST SYS KIT GM100	KROGER BGM KIT PREMIUM
QUICKTEK KIT	RIGHTEST SYS KIT GM550	CONTOUR KIT LINK 2.4
ADVANCE KIT INTUITIO	IGLUCOSE KIT	EASYMAX V KIT SYSTEM
GLUCOCARD KIT SHNE CON	NOVA MAX KIT SYSTEM	EASYMAX NG KIT SYSTEM
GLUCOCARD KIT SHNE EXP	WAVESENSE KIT KEYNOTE	MYGLUCOHEALT KIT SYSTEM
GLUCOCARD KIT EXPRESSI	AGAMA JAZZ KIT WRLSS 2	MICRODOT KIT SYSTEM
POCKETCHEM KIT EZ	AGAMATRIX KIT PRESTO	ONE TOUCH KIT VERIO FL

GLUCOCARD 01 KIT SYSTEM	WAVESENSE KIT AMP	RELION TRUE KIT MET AIR
GLUCOCARD 01 KIT MINI	SOLUS V2 KIT SYSTEM	VERASENS KIT
GLUCOCARD KIT X-METER	COOL MONITOR KIT	INFINITY KIT VOICE
GLUCOCARD KIT VITAL	TRUERESULT KIT MONITOR	OPTIUM KIT BL GLUC
RELION PREMI KIT COMP SYS	TRUERESULT KIT SYSTEM	PRECISION KIT XTRA
SMART SENSE KIT GLUC SYS	MEIJER BGM KIT ESSENTIA	PRECISION KIT LINK
CVS GLUCOSE KIT METER	MEIJER GLUCO KIT MONITOR	BIOTEL CARE KIT SYSTEM
INFINITY KIT SYSTEM	MEIJER BGM KIT PREMIUM	BIOTEL CARE KIT
EASYPRO KIT MONITOR	FORA V30A KIT	FREESTYLE KIT SIDEKICK
EASYPRO PLUS KIT	FORA TN'G KIT VOICE	FREESTYLE KIT FREEDOM
PRODIGY PCKT KIT METER	REFUAH PLUS KIT SYSTEM	KROGER BGM KIT PREMIUM
PRODIGY AUTO KIT MONITOR	KROGER BGM KIT	CONTOUR KIT LINK 2.4
PRODIGY VOIC KIT METER		
PRODIGY KIT NO CODIN		

3 . Revision History

Date	Notes
8/26/2022	C&S to match AZM 10.1.22

Bonjesta and Diclegis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64357
Guideline Name	Bonjesta and Diclegis
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Bonjesta, Brand Diclegis, generic doxylamine/pyridoxine	
Diagnosis	Nausea and vomiting associated with pregnancy
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nausea and vomiting associated with pregnancy

AND

2 - Documented failure or contraindication to lifestyle modifications (e.g., diet, avoidance of triggers)

AND

3 - Documented trial and failure or contraindication to a five day trial of over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly)

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Breast Cancer

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110348
Guideline Name	Breast Cancer
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Arimidex, generic anastrozole	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Adjuvant treatment of postmenopausal patients with hormone receptor-positive early breast cancer

OR

1.2 First-line treatment of postmenopausal patients with hormone receptor-positive or hormone receptor status unknown locally advanced or metastatic breast cancer

OR

1.3 Postmenopausal patients with disease progression following tamoxifen therapy

Product Name: Brand Aromasin, generic exemestane	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Adjuvant treatment of postmenopausal patients with estrogen receptor-positive early breast cancer who have received 2 to 3 years of tamoxifen and are switched to exemestane for completion of a total of 5 consecutive years of adjuvant hormonal therapy

OR

1.2 Treatment of advanced breast cancer in postmenopausal patients whose disease has progressed following tamoxifen therapy

Product Name: Brand Fareston, generic toremifene	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of metastatic breast cancer in postmenopausal patients with estrogen receptor positive tumors or with tumors of unknown estrogen receptor status

Product Name: Brand Arimidex, generic anastrozole, Brand Aromasin, generic exemestane, Brand Fareston, generic toremifene	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Arimidex, generic anastrozole, Brand Aromasin, generic exemestane, Brand Fareston, generic toremifene	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Breo Ellipta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127703
Guideline Name	Breo Ellipta
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Breo Ellipta, generic fluticasone-vilanterol	
Diagnosis	Asthma, COPD
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of asthma

AND

1.2 Patient is 5 years of age or older

AND

1.3 The patient has a history of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Symbicort

OR

2 - ALL of the following:

2.1 Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2.2 Patient is 18 years of age or older

AND

2.3 ONE of the following:

2.3.1 History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent (e.g., Spiriva, Atrovent, Combivent, Tudorza)

OR

2.3.2 History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent/long-acting beta-agonist combination agent (e.g., Anoro Ellipta, Stiolto Respimat)

AND

2.4 The patient has a history of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Symbicort

2 . Revision History

Date	Notes
7/7/2023	Added generic, added age criteria

Brexafemme

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120893
Guideline Name	Brexafemme
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Brexafemme	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to BOTH of the following:

- One intravaginal product (e.g., clotrimazole, miconazole, tioconazole, terconazole, boric acid)
- Oral fluconazole for a minimum of 3 days duration

2 . Revision History

Date	Notes
2/3/2023	Updated all criteria and approval duration.

Brilinta and Effient

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110358
Guideline Name	Brilinta and Effient
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Brilinta, Brand Effient, Generic prasurgrel	
Diagnosis	Acute coronary syndrome (ACS)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]

AND

2 - If request is for Effient (prasugrel), patient must be managed with percutaneous coronary intervention (PCI)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Bronchitol

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124642
Guideline Name	Bronchitol
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Bronchitol	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Used in conjunction with standard CF therapies [e.g., chest physiotherapy,

bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]

AND

3 - Patient has passed the Bronchitol Tolerance Test

Product Name: Bronchitol	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bronchitol therapy

Buprenorphine Sublingual Tablet

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-122047
Guideline Name	Buprenorphine Sublingual Tablet
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: buprenorphine SL tablets	
Approval Length	6 Months*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of opioid abuse/dependence

AND

2 - ONE of the following:

2.1 Patient is pregnant or breastfeeding*

OR

2.2 BOTH of the following:

2.2.1 Patient had an intolerance or side effect to buprenorphine-naloxone sublingual tablet or film

AND

2.2.2 Side effects or intolerances to buprenorphine-naloxone sublingual tablet or films were not resolved with a trial of anti-emetics (e.g., ondansetron) or non-opioid analgesics

OR

2.3 Patient has a contraindication to naloxone

OR

2.4 BOTH of the following:

2.4.1 Patient has a severe allergy to naloxone [e.g., Stevens-Johnson syndrome, DRESS (Drug Rash with Eosinophilia and Systemic Symptoms)]

AND

2.4.2 Provider has submitted a copy of the MedWatch Form 3500 to the Food and Drug Administration documenting the adverse reaction

AND

3 - Patient is not currently on ANY of the following:

- Benzodiazepines (e.g., Alprazolam, Diazepam, Lorazepam)
- Hypnotics (e.g., Temazepam, Rozerem, Zolpidem)

• Opioids (e.g., Oxycodone, Tramadol, Hydrocodone) **AND** **4** - Prescriber attests that the Arizona State Board of Pharmacy Controlled Substance Prescription Drug Monitoring Program database has been reviewed and that patient has been warned about the dangers of ingesting concurrent sedating medications	
Notes	*Approve for 1 year if pregnant or breastfeeding

2 . Revision History

Date	Notes
3/6/2023	Removed X waiver DEA criteria, cleaned up criteria and product nam e list.

Bylvay (odevixibat)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132795
Guideline Name	Bylvay (odevixibat)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 confirmed by ONE of the following:

- Diagnostic test (e.g., liver function test, liver ultrasound and biopsy, bile analysis)

- Genetic Testing

AND

2 - Patient is experiencing BOTH of the following:

- Moderate to severe pruritus
- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 3 months of age or older

AND

4 - Patient has had an inadequate response to at least TWO of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed dose is consistent with FDA (Food and Drug Administration)-approved package labeling and does not exceed a total daily dose of 6 mg (milligrams)

AND

6 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name: Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced serum bile acids, improved pruritus)

AND

2 - Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6 mg

Product Name: Bylvay	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene

AND

2 - Patient is experiencing BOTH of the following:

- Moderate to severe pruritus

- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 12 months of age or older

AND

4 - Patient has had an inadequate response to at least TWO of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name: Bylvay	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

2 . Revision History

Date	Notes
9/11/2023	Added criteria for new indication Alagille Syndrome

Cablivi

Prior Authorization Guideline

Guideline ID	GL-86294
Guideline Name	Cablivi
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)	

AND

2 - Cablivi was initiated as a bolus intravenous injection administered by a healthcare provider in combination with plasma exchange therapy

AND

3 - Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)

AND

4 - Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) (Documentation of date of prior episode and documentation date of new episode required)

2 . Revision History

Date	Notes
4/30/2021	Copy of NY

Cabotegravir Containing Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132798
Guideline Name	Cabotegravir Containing Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Vocabria	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV (human immunodeficiency virus)-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kilograms

AND

1.4 Patient is currently virologically suppressed [HIV-1 RNA (ribonucleic acid) less than 50 copies/milliliter] on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

Product Name: Vocabria	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV (human immunodeficiency virus)-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kilograms

AND

3 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to use:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA (ribonucleic acid) assay

AND

4 - One of the following:

4.1 Trial and failure, contraindication or intolerance to BOTH of the following:

- Brand Truvada
- Descovy

OR

4.2 Submission of medical records (e.g., chart notes) from provider documenting BOTH of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Product Name: Vocabria	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

2 . Revision History

Date	Notes
9/11/2023	Updated T/F criteria verbiage for PrEP indication.

Camzyos (mavacamten)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115886
Guideline Name	Camzyos (mavacamten)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Camzyos	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain)

AND

3 - Patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose:

- non-vasodilating beta blocker (e.g., bisoprolol, propranolol)
- calcium channel blocker (e.g., verapamil, diltiazem)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved symptom relief)

AND **2** - Patient has a left ventricular ejection fraction of greater than or equal to 50% **AND** **3** - Prescribed by or in consultation with a cardiologist

2 . Revision History

Date	Notes
10/21/2022	New GL

Caplyta (lumateperone), Rexulti (brexpiprazole), Vraylar (cariprazine)

Prior Authorization Guideline

Guideline ID	GL-127738
Guideline Name	Caplyta (lumateperone), Rexulti (brexpiprazole), Vraylar (cariprazine)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Caplyta, Rexulti, Vraylar	
Diagnosis	Schizophrenia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of schizophrenia

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to at least FOUR of the following preferred alternatives:

- Aripiprazole oral (generic Abilify)
- Aripiprazole injectable formulations (Abilify Maintena, Aristada, Aristada Initio)
- Clozapine/clozapine ODT (orally disintegrating tablet)
- Lurasidone
- Olanzapine/olanzapine ODT
- Paliperidone oral
- Paliperidone injectable formulations (Invega Sustenna, Invega Trinza, Hafyera)
- Quetiapine
- Risperidone/risperidone ODT
- Risperidone injectable formulations (Perseris, Risperdal Consta)

OR

2.2 ONE of the following:

2.2.1 The patient has been receiving treatment with the requested medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Vraylar	
Diagnosis	Bipolar I Disorder
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bipolar I disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to ALL of the following preferred alternatives:

- Lamotrigine
- Lithium
- Valproate

AND

2.1.2 History of failure, contraindication, or intolerance to THREE of the following preferred alternatives:

- Aripiprazole
- Lurasidone
- Quetiapine
- Risperidone

OR

2.2 ONE of the following:

2.2.1 The patient has been receiving treatment with the requested medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Caplyta, Vraylar	
Diagnosis	Bipolar Depression
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bipolar depression

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to at least FOUR of the following preferred alternatives:

- Fluoxetine
- Lamotrigine
- Lithium ER
- Lurasidone
- Paroxetine
- Quetiapine
- Valproate
- Combination Therapy (i.e., lithium plus lamotrigine/valproate, lurasidone plus lithium/valproate, olanzapine plus fluoxetine, quetiapine plus lithium/valproate)

OR

2.2 ONE of the following:

2.2.1 The patient has been receiving treatment with the requested medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Rexulti, Vraylar	
Diagnosis	Major Depressive Disorder (MDD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of major depressive disorder (MDD)

OR

1.2 If the request is for Vraylar, diagnosis of treatment resistant depression

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to at least THREE of the following preferred alternatives:

- Bupropion
- Citalopram
- Duloxetine 20 mg, 30 mg, or 60 mg
- Escitalopram tablets
- Fluoxetine
- Fluvoxamine tablets
- Paroxetine IR tablets
- Sertraline tablets or oral concentrate for solution
- Venlafaxine IR tablets or Venlafaxine ER capsules

AND

2.1.2 History of failure, contraindication, or intolerance to ALL of the following:

- Aripiprazole
- Quetiapine ER
- Risperidone

OR

2.2 ONE of the following:

2.2.1 The patient has been receiving treatment with the requested medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Rexulti	
Diagnosis	Agitation Associated with Dementia Due to Alzheimer's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication is being used for treatment of agitation associated with dementia due to Alzheimer's disease

Product Name: Caplyta	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from one of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential patient outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data, and pharmacoeconomic studies
- Other drug reference resources

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The requested dose falls within dosing guidelines found in ONE of the following compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential patient outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data, and pharmacoeconomic studies
- Other drug reference resources

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

5 - Physician has provided rationale for needing to exceed the quantity limit of one capsule [42 milligrams (mg)] per day (NOTE: The treatment effect of Caplyta 84 mg daily versus placebo was NOT statistically significant in clinical trials)

2 . Revision History

Date	Notes
7/7/2023	Updated guideline name, GPI and product name lists, updated all crit eria and most indications.

Carbaglu (carglumic acid)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110589
Guideline Name	Carbaglu (carglumic acid)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g., protein restriction, ammonia scavengers, dialysis)

AND

3 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g. intravenous glucose, insulin, protein restriction, dialysis)

AND

3 - Patient’s plasma ammonia level is greater than or equal to 50 micromol/L

AND

4 - Medication will be used for a maximum duration of 7 days

AND

5 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - NAGS deficiency has been confirmed by genetic/mutational analysis

AND

3 - Medication will be used as maintenance therapy

AND

4 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid

Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a positive clinical response to therapy (e.g., plasma ammonia level within the normal range)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Cayston

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64446
Guideline Name	Cayston
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Cayston	
Diagnosis	Cystic Fibrosis (CF)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Ceprotin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-105534
Guideline Name	Ceprotin
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Ceprotin	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe congenital Protein C deficiency

AND

2 - Medication is being used for prevention or treatment of venous thrombosis and/or purpura fulminans

AND

3 - Medical record documentation of ONE of the following:

- Low protein C activity
- Low protein C antigen
- Genetic testing demonstrating biallelic mutations in the PROC gene

AND

4 - Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of Protein C deficiency

AND

5 - Dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling and is adjusted based on the patient's weight, severity of deficiency, and whether treatment is for acute episodes or prophylaxis

Product Name: Ceprotin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received Ceprotin

AND

2 - Documentation of positive clinical response to Ceprotin

AND **3** - Dosing is in accordance with the FDA approved labeling and is adjusted based on the patient's weight, severity of deficiency, and whether treatment is for acute episodes or prophylaxis

2 . Revision History

Date	Notes
3/31/2022	New Guideline

CGRP Inhibitors

Prior Authorization Guideline

Guideline ID	GL-134161
Guideline Name	CGRP Inhibitors
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Ajovy, Emgality 120 mg/ml	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month

OR

1.2 ALL of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued

AND

2 - Patient is 18 years of age or older

AND

3 - TWO of the following:

3.1 ONE of the following:

3.1.1 History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)

OR

3.1.2 Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 ONE of the following:

3.2.1 History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)

OR

3.2.2 Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 ONE of the following:

3.3.1 History of failure (after at least a two month trial) or intolerance to ONE of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol

OR

3.3.2 Patient has a contraindication to ALL of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

AND

4 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Ajovy, Emgality 120 mg/ml	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH)

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist

- Pain specialist
- Headache specialist*

AND

5 - Medication will not be used in combination with another injectable CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

3 - Medication will not be used in combination with another injectable CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Aimovig, Qulipta, Vyepti

Diagnosis	Preventive Treatment of Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month

OR

1.2 ALL of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued

AND

2 - Patient is 18 years of age or older

AND

3 - TWO of the following:

3.1 ONE of the following:

3.1.1 History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)

OR

3.1.2 Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 ONE of the following:

3.2.1 History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)

OR

3.2.2 Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 ONE of the following:

3.3.1 History of failure (after at least a two month trial) or intolerance to ONE of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol

OR

3.3.2 Patient has a contraindication to ALL of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

AND

4 - Trial and failure, contraindication, or intolerance to BOTH of the following:

- Ajovy
- Emgality

AND

5 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Aimovig, Qulipta, Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP (calcitonin gene-related peptide) therapy

AND

3 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH)

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month

AND

2 - Patient is 18 years of age or older

AND

3 - TWO of the following

3.1 ONE of the following:

3.1.1 History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)

OR

3.1.2 Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 ONE of the following:

3.2.1 History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)

OR

3.2.2 Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 ONE of the following:

3.3.1 History of failure (after at least a two month trial) or intolerance to ONE of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol

OR

3.3.2 Patient has a contraindication to ALL of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

AND

4 - Trial and failure, contraindication, or intolerance to BOTH of the following:

- Ajovy
- Emgality

AND

5 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Nurtec ODT, Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has fewer than 15 headache days per month

AND

4 - Patient is 18 years of age or older

AND

5 - Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to FOUR of the following as evidenced by submission of medical records or claims history:

- naratriptan tablets
- rizatriptan tablets/ODT (Oral Disintegrating Tablets)
- sumatriptan auto injection/cartridge
- Imitrex nasal spray (Brand only)
- zolmitriptan tablets/ODT
- Zomig nasal spray (Brand only)

AND

6 - Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to Ubrelvy as evidenced by submission of medical records or claims history**

AND

7 - If patient has 4 or more headache days per month, patient must meet ONE of the following:

7.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

7.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

7.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

AND

8 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

9 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS). **Patients requesting initial authorization who were established on the rapy via the receipt of a manufacturer supplied sample at no cost in th e prescriber's office or any form of assistance from the manufacturer s ponsored programs shall be required to meet initial authorization criter ia as if patient were new to therapy.

Product Name: Nurtec ODT, Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

3 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Will not be used for preventive treatment of migraine

AND

4 - Patient has fewer than 15 headache days per month

AND

5 - Patient is 18 years of age or older

AND

6 - Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to TWO of the following as evidenced by submission of medical records or claims history:

- naratriptan tablets
- rizatriptan tablets/ODT (Oral Disintegrating Tablets)
- sumatriptan auto injection/cartridge
- zolmitriptan tablets/ODT
- Zomig nasal spray (Brand only)
- Imitrex nasal spray (Brand only)

AND

7 - If patient has 4 or more headache days per month, patient must meet ONE of the following:

7.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

7.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

7.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

AND

8 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

9 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Prescribed by or in consultation with ONE of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

2 . Revision History

Date	Notes
10/3/2023	Updated criteria GPI and product name lists to move Aimovig around , updated T/F criteria to remove Aimovig.

Cholbam

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110663
Guideline Name	Cholbam
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Cholbam	
Diagnosis	Bile Acid Synthesis Disorder
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a bile acid synthesis disorder

AND

2 - It is due to single enzyme defects

Product Name: Cholbam	
Diagnosis	Peroxisomal Disorders Including Zellweger Spectrum Disorders
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of peroxisomal disorders including Zellweger spectrum disorders

AND

2 - Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption

AND

3 - It is being used as adjunctive treatment

Product Name: Cholbam	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cholbam therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Cialis for BPH

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110850
Guideline Name	Cialis for BPH
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Cialis 5mg, generic tadalafil 5mg	
Diagnosis	Benign Prostatic Hyperplasia (BPH)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 The patient has a diagnosis of benign prostatic hyperplasia (BPH)

AND

1.2 History of failure, intolerance, or contraindication to BOTH of the following:

- Alpha Blockers (e.g., tamsulosin, alfuzosin ER, doxazosin, or terazosin)
- 5-alpha reductase inhibitors (e.g., finasteride)

AND

1.3 Dose does not exceed 5 milligrams once daily

AND

2 - Provider attests that patient is not using any form of organic nitrate (for example, nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas

2 . Revision History

Date	Notes
8/9/2022	C&S to match AZM 10.1.22

Cibinqo (abrocitinib)

Prior Authorization Guideline

Guideline ID	GL-122722
Guideline Name	Cibinqo (abrocitinib)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Cibinqo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

4 - History of failure, contraindication, or intolerance to BOTH of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole) ointment

AND

5 - Trial and failure of a minimum 12-week supply, intolerance, or contraindication to Dupixent (dupilumab) for the treatment of atopic dermatitis

AND

6 - Not used in combination with biologic immunomodulators (e.g., Dupixent, Adbry) or other immunosuppressants (e.g., azathioprine, cyclosporine)

AND

7 - Patient is 12 years of age or older

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and/or contraindication to medication

Product Name: Cibinqo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline

AND

2 - Not used in combination with biologic immunomodulators (e.g., Dupixent, Adbry) or other immunosuppressants (e.g., azathioprine, cyclosporine)

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
	Amcinonide	Cream, lotion, ointment	0.1

High Potency	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01

Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
3/10/2023	Added age criterion and updated embedded step requirements

Cimzia

Prior Authorization Guideline

Guideline ID	GL-127759
Guideline Name	Cimzia
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Crohn’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active Crohn’s disease

AND

1.2 History of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

AND

1.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to Humira (adalimumab)

AND

1.5 Prescribed by or in consultation with a gastroenterologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of Crohn's disease

AND

2.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Cimzia, Cimzia Starter Kit

Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to THREE of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.5 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

AND

1.2 History of failure to two NSAIDs [non-steroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen)] at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

AND

2.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials.

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.4 History of failure of a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.5 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.6 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilsat)

AND

1.7 Prescribed by or in consultation with a dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderate to severe plaque psoriasis

AND

2.3 Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials.

Product Name: Cimzia, Cimzia Starter Kit	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with any of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
7/7/2023	Updated guideline name, updated GPI and product name lists, clean ed up criteria, numbering, and notes.

Colony Stimulating Factors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126345
Guideline Name	Colony Stimulating Factors
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Nivestym, Leukine, Neupogen, Releuko, Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Nivestym

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Nivestym, Leukine, Neupogen, Releuko, Zarxio	
Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has completed either induction or consolidation chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Nivestym

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Nivestym, Ziextenzo, Fulphila, Leukine, Neulasta, Neulasta Onpro, Neupogen, Nyvepria, Udenyca, Zarxio	
Diagnosis	Neutropenia Associated with Cancer Chemotherapy - Dose Dense Chemotherapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Nivestym and Ziextenzo

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Fylnetra, Nivestym, Ziextenzo, Fulphila, Granix, Neulasta, Neulasta Onpro, Neupogen, Nyvepria, Stimufend, Udenyca, Zarxio	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20 percent incidence of febrile neutropenia (FN)

OR

1.2 BOTH of the following:

- Patient is receiving chemotherapy regimen(s) associated with 10-20 percent incidence of FN
- Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Fylnetra, Nivestym, and Ziextenzo

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Nivestym, Ziextenzo, Fulphila, Granix, Neulasta, Neulasta Onpro, Neupogen, Nyvepria, Stimufend, Udenyca, Zarxio	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia [absolute neutrophil count (ANC) less than or equal to 500 cells per mm^3 (cubic millimeter)]

AND

2 - Patient has a history of febrile neutropenia (FN) during a previous course of chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Nivestym and Ziextenzo

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Fylnetra, Nivestym, Ziextenzo, Fulphila, Leukine, Neulasta, Neulasta Onpro, Neupogen, Nyvepria, Stimufend, Udenyca, Zarxio	
Diagnosis	Treatment of Febrile Neutropenia (FN) (off-label)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia [absolute neutrophil count (ANC) less than or equal to 500 cells per mm^3 (cubic millimeter)]

AND

2 - Diagnosis of febrile neutropenia (FN) and patient is considered high risk for infection-associated complications

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Fylnetra, Nivestym, and Ziextenzo

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Nivestym, Neupogen, Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe chronic neutropenia (SCN) [i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count (ANC) less than or equal to 500 cells per mm^3 (cubic millimeter)]

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Nivestym

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Nivestym, Leukine, Neupogen, Zarxio	
Diagnosis	HIV-Related Neutropenia (off-label)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV) infection

AND

2 - Patient has an absolute neutrophil count (ANC) less than or equal to 1,000 cells per mm^3

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist
- Infectious disease specialist

AND

4 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Nivestym

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Nivestym, Neupogen, Zarxio	
Diagnosis	Hepatitis C Treatment Related Neutropenia (off-label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

- Diagnosis of hepatitis C virus
- Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)
- Documentation of neutropenia [absolute neutrophil count (ANC) less than or equal to 500 cells per mm^3] after dose reduction of Peg-Intron or Pegasys

OR

1.2 BOTH of the following:

1.2.1 Documentation of interferon-induced neutropenia (ANC less than or equal to 500 cells per mm^3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 ONE of the following:

- Diagnosis of human immunodeficiency virus (HIV) co-infection
- Status post liver transplant
- Diagnosis of established cirrhosis

AND

2 - Prescribed by, or in consultation with, a hematologist, oncologist, gastroenterologist, hepatologist, or infectious disease specialist

AND

3 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Nivestym

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Fylnetra, Nivestym, Ziextenzo, Fulphila, Leukine, Neulasta, Neulasta Onpro, Neupogen, Nyvepria, Stimufend, Udenyca, Zarxio	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND **3** - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to Fylnetra, Nivestym, and Ziextenzo	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
6/6/2023	Updated GPI lists and added new GPI for Udenyca, corrected spelling in product name list.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121149
Guideline Name	Combination Basal Insulin-GLP-1 Receptor Agonist
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Soliqua	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Inadequately controlled on BOTH of the following

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g., Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]
- Basal insulin (e.g., insulin glargine, insulin degludec, insulin detemir)

Product Name: Xultophy	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - Inadequately controlled on BOTH of the following:

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g., Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]
- Basal insulin (e.g., insulin glargine, insulin degludec, insulin detemir)

AND

3 - History of failure, intolerance, or contraindication to Soliqua

Product Name: Xultophy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xultophy therapy

2 . Revision History

Date	Notes
2/9/2023	Removed TD criteria section.

Compounds and Bulk Powders

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110362
Guideline Name	Compounds and Bulk Powders
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Requests for Compounds or Bulk Powders	
Approval Length	2 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 The compound is an antibiotic.

OR

1.2 Each active ingredient in the compounded drug is a covered medication

AND

2 - ONE of the following:

2.1 Each active ingredient in the compounded drug is to be administered for an FDA (Food and Drug Administration)-approved indication

OR

2.2 The use of each active ingredient in the compounded drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons.

AND

5 - ONE of the following:

5.1 A unique vehicle is required for topically administered compounds

OR

5.2 A unique dosage form is required for a commercially available product due to patient's age, weight, or inability to take a solid dosage form

OR

5.3 A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

OR

5.4 There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP Current Drug Shortages tracking log

AND

6 - Coverage for compounds and bulk powders will NOT be approved for any of the following:

6.1 For topical compound preparations (e.g. creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous, or any other topical route), requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use (see Table 1 in Background section)

OR

6.2 If the requested compound contains topical fluticasone, topical fluticasone will NOT be approved unless both of the following are met:

6.2.1 Topical fluticasone is intended to treat a dermatologic condition (scar treatments are considered cosmetic and will not be covered)

AND

6.2.2 Patient has a contraindication to all commercially available topical fluticasone formulations

OR

6.3 Requested compound contains any ingredients when used for cosmetic purposes (see Table 2 in Background section)

OR

6.4 Requested compound contains any ingredient(s) which are on the FDA's Do Not Compound List (see Table 3 in Background section)

2 . Background

Benefit/Coverage/Program Information

Table 1: Example topical compound preparations that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

(1) Ketamine

(2) Gabapentin

(3) Flurbiprofen (topical ophthalmic use not included)

(4) Ketoprofen

(5) Morphine

(6) Nabumetone

(7) Oxycodone

(8) Cyclobenzaprine

(9) Baclofen

(10) Tramadol

(11) Hydrocodone

(12) Meloxicam

(13) Amitriptyline

(14) Pentoxifylline

(15) Orphenadrine

(16) Piroxicam

(17) Levocetirizine

(18) Amantadine

(19) Oxytocin

(20) Sumatriptan

(21) Chorionic gonadotropin (human)

(22) Clomipramine

(23) Dexamethasone

(24) Hydromorphone

(25) Methadone

(26) Papaverine

(27) Mefenamic acid

(28) Promethazine

(29) Succimer DMSA

(30) Tizanidine

(31) Apomorphine

(32) Carbamazepine

(33) Ketorolac

(34) Dimercaptopropane-sulfonate

(35) Dimercaptosuccinic acid

(36) Duloxetine

(37) Fluoxetine

(38) Bromfenac (topical ophthalmic use not included)

(39) Nepafenac (topical ophthalmic use not included)

Table 2: Example compounds that contain ingredients for cosmetic purposes:

(1) Hydroquinone

(2) Acetyl hexapeptide-8

(3) Tocopheryl Acid Succinate

(4) PracaSil TM-Plus

(5) Chrysaderm Day Cream

(6) Chrysaderm Night Cream

(7) PCCA Spira-Wash

(8) Lipopen Ultra

(9) Versapro

(10) Fluticasone

(11) Mometasone

(12) Halobetasol

(13) Betamethasone

(14) Clobetasol

(15) Triamcinolone

(16) Minoxidil

(17) Tretinoin

(18) Dexamethasone

(19) Spironolactone

(20) Cycloserine

(21) Tamoxifen

(22) Sermorelin

(23) Mederma Cream

(24) PCCA Cosmetic HRT Base

(25) Sanare Scar Therapy Cream

(26) Scarcin Cream

(27) Apothederm

(28) Stera Cream

(29) Copasil

(30) Collagenase

(31) Arbutin Alpha

(32) Nourisil

(33) Freedom Cepapro

(34) Freedom Silomac Andydrous

(35) Retinaldehyde

(36) Apothederm

Table 3: Example ingredients on the FDA's Do Not Compound List:

(1) 3,3′,4′,5-tetrachlorosalicylanilide

(2) Adenosine phosphate

(3) Adrenal cortex

(4) Alatrofloxacin mesylate

(5) Aminopyrine

(6) Astemizole

(7) Azaribine

(8) Benoxaprofen

(9) Bithionol

(10) Camphorated oil

(11) Carbetapentane citrate

(12) Casein, iodinated

(13) Cerivastatin sodium

(14) Chlormadinone acetate

(15) Chloroform

(16) Cisapride

(17) Defenfluramine hydrochloride

(18) Diamthazole dihydrochloride

(19) Dibromsalan

(20) Dihydrostreptomycin sulfate

(21) Dipyrone

(22) Encainide hydrochloride

(23) Etretinate

(24) Fenfluramine hydrochloride

(25) Flosequinan

(26) Glycerol, iodinated

(27) Grepafloxacin

(28) Mepazine

(29) Metabromsalan

(30) Methapyrilene

(31) Methopholine

(32) Methoxyflurane

(33) Mibefradil dihydrochloride

(34) Nomifensine maleate

(35) Novobiocin sodium

(36) Oxyphenisatin acetate

(37) Oxyphenisatin

(38) Pemoline

(39) Pergolide mesylate

(40) Phenacetin

(41) Phenformin hydrochloride

(42) Phenylpropanolamine

(43) Pipamazine

(44) Potassium arsenite

(45) Propoxyphene

(46) Rapacuronium bromide

(47) Rofecoxib

(48) Sibutramine hydrochloride

(49) Sparteine sulfate

(50) Sulfadimethoxine

(51) Sweet spirits of nitre

(52) Tegaserod maleate

(53) Temafloxacin hydrochloride

(54) Terfenadine

(55) Ticrynafen

(56) Tribromsalan

(57) Trichloroethane

(58) Troglitazone

(59) Trovafloxacin mesylate:

(60) Urethane

(61) Valdecoxib

(62) Zomepirac sodium

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Constipation Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132854
Guideline Name	Constipation Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Brand Amitiza, generic lubiprostone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ONE of the following diagnoses:

- Opioid-induced constipation in an adult with chronic, non-cancer pain
- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

- Chronic idiopathic constipation

OR

1.2 Both of the following:

- Diagnosis of irritable bowel syndrome with constipation
- Patient was female at birth

AND

2 - BOTH of the following:

2.1 Trial and failure, contraindication, or intolerance to an osmotic laxative (e.g., lactulose, polyethylene glycol, sorbitol)

AND

2.2 Trial and failure, contraindication, or intolerance to ONE of the following:

- Bulk Forming Laxatives (e.g., psyllium, fiber)
- Stimulant Laxatives (e.g., bisacodyl, senna)

Product Name: Ibsrela	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - History of failure, contraindication, or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - History of failure, contraindication, or intolerance to ONE of the following:

- Lubiprostone
- Linzess

Product Name: Linzess	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 ONE of the following diagnoses:

- Chronic idiopathic constipation
- Irritable bowel syndrome with constipation

AND

1.1.2 Patient is greater than or equal to 18 years of age

OR

1.2 All of the following:

- Diagnosis of functional constipation
- Patient is 6-17 years of age
- The request is for Linzess 72mg

AND

2 - Both of the following:

2.1 Trial and failure, contraindication, or intolerance to an osmotic laxative (e.g., (lactulose, polyethylene glycol, sorbitol)

AND

2.2 Trial and failure, contraindication, or intolerance to ONE of the following:

- Bulk Forming Laxatives (e.g., psyllium, fiber)
- Stimulant Laxatives (e.g., bisacodyl, senna)

Product Name: Motegrity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic constipation

AND

2 - Both of the following:

2.1 History of failure, contraindication, or intolerance to BOTH of the following:

- Lactulose

- Polyethylene glycol (Miralax)

AND

2.2 History of failure, contraindication, or intolerance to BOTH of the following:

- Linzess
- Lubiprostone

Product Name: Movantik	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Opioid-induced constipation in patients being treated for chronic, non-cancer pain
- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

Product Name: Relistor tablet, Relistor injection, Symproic	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Opioid-induced constipation in patients being treated for chronic, non-cancer pain

- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2 - History of failure, contraindication, or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - History of failure, contraindication, or intolerance to Movantik

AND

4 - For Relistor Injection requests ONLY: The patient is not able to swallow oral medications

Product Name: Trulance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Chronic idiopathic constipation
- Irritable bowel syndrome with constipation

AND

2 - Patient is greater than or equal to 18 years of age

Product Name: Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - Patient was female at birth

AND

3 - History of failure, contraindication, or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

4 - History of failure, contraindication, or intolerance to ONE of the following:

- Lubiprostone
- Linzess

Product Name: Brand Amitiza, generic lubiprostone, Ibsrela, Linzess, Motegrity, Movantik, Relistor tablet, Relistor injection, Symproic, Trulance, Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/11/2023	Added criteria for Linzess 72mg new indication of functional constipation.

Copper Chelating Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136002
Guideline Name	Copper Chelating Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe active rheumatoid arthritis	

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Depen Titratabs therapy

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)
- Diagnosis of Cystinuria

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Wilson's disease (i.e., hepatolenticular degeneration)
- Cystinuria

- Severe active rheumatoid arthritis

AND

2 - History of failure or intolerance to Depen (penicillamine)

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cuprimine (penicillamine) therapy

Product Name: Brand Syprine, generic trientine, generic Clovique	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - History of failure, contraindication, or intolerance to Depen (penicillamine) or Cuprimine (penicillamine)

Product Name: Brand Syprine, generic trientine, generic Clovique	
Diagnosis	Wilson’s disease (i.e., hepatolenticular degeneration)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Syprine (trientine) therapy	

2 . Revision History

Date	Notes
11/6/2023	Added new GPI for trientine

Corlanor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64362
Guideline Name	Corlanor
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Worsening heart failure in a diagnosis of stable, symptomatic chronic (e.g. New York Heart Association (NYHA) class II, III or IV) heart failure

AND

2 - Patient has a left ventricular ejection fraction (EF) less than or equal to 35%

AND

3 - The patient is in sinus rhythm

AND

4 - Patient has a resting heart rate greater than or equal to 70 beats per minute

AND

5 - ONE of the following:

5.1 Patient is on maximum tolerated doses of beta blockers (e.g., carvedilol, metoprolol succinate, bisoprolol)

OR

5.2 Patient has a contraindication or intolerance to beta-blocker therapy

Product Name: Corlanor	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy (DCM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM)

AND **2** - Patient is in sinus rhythm **AND** **3** - Patient has an elevated heart rate

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure, Heart Failure due to Dilated Cardiomyopathy (DCM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Corlanor therapy	

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Cosentyx (secukinumab)

Prior Authorization Guideline

Guideline ID	GL-137448
Guideline Name	Cosentyx (secukinumab)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Cosentyx SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 Both of the following:

1.3.1 History of failure to TWO of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following:

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Otezla (apremilast)

AND

2 - Patient is 6 years of age or older

AND

3 - Prescribed by, or in consultation with, a dermatologist

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by, or in consultation with, a dermatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Ankylosing Spondylitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following:*

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Xeljanz (tofacitinib) oral tablet

AND

2 - Prescribed by, or in consultation with, a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by, or in consultation with, a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

AND

1.3 History of failure, contraindication, or intolerance to THREE of the following:

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) oral tablet

AND

2 - Patient is 2 years of age or older

AND

3 - Prescribed by, or in consultation with, one of the following:

- Rheumatologist
- Dermatologist

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Xeljanz (tofacitinib) oral tablet

AND

2 - Prescribed by, or in consultation with, a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by, or in consultation with, a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting BOTH of the following:

1.1 Diagnosis of active enthesitis-related arthritis

AND

1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO preferred non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by, or in consultation with, a rheumatologist

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least one of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Prescribed by, or in consultation with, a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

2 . Revision History

Date	Notes
12/7/2023	Removed CoT for all indications. Updated preferred t/f. Updated verb iage for concomitant immunosuppressives criterion.

Cough and Cold Products

Prior Authorization Guideline

Guideline ID	GL-110287
Guideline Name	Cough and Cold Products
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Hydromet, generic Tussigon, Z-Tuss AC, Tuzistra XR, Tussicaps, generic Tussionex, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss, generic promethazine w/codeine, generic promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP/Mar-Cof GG, Ninjacof-XG, Coditussin AC/Coditussin DAC, generic guaifenesin-codeine, generic pseudoephedrine w/codeine-guaifenesin, Tuxarin ER	
Diagnosis	Under the Age of 18 Years for Cough and Cold Products
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prescriber attests they are aware of Food and Drug Administration (FDA) labeled contraindications regarding use of opioid containing cough and cold products in patients less	

than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

AND

2 - Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index greater than 30)

AND

3 - Patient has tried and failed at least one non-opioid containing cough and cold remedy

Product Name: Hydromet, generic Tussigon, Z-Tuss AC, Tuzistra XR, Tussicaps, generic Tussionex, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss, generic promethazine w/codeine, generic promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP/Mar-Cof GG, Ninjacof-XG, Coditussin AC/Coditussin DAC, generic guaifenesin-codeine, generic pseudoephedrine w/codeine-guaifenesin, Tuxarin ER	
Diagnosis	Quantity Limit
Approval Length	30 Day(s)
Guideline Type	Quantity Limit*

Approval Criteria

1 - Prescriber attests that a larger quantity is medically necessary

AND

2 - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (See table in background section)

Notes	*Authorization will be issued for up to 30 days. The authorization should be entered for the quantity requested.

2 . Background

Benefit/Coverage/Program Information

CDC Recommended Opioid Maximum Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses
Morphine	None
Hydromorphone	None
Hydrocodone	None
Tapentadol	600mg IR products
Oxymorphone	None
Oxycodone	None
Codeine	360mg
Pentazocine	None
Tramadol	400mg IR products
Meperidine	600mg
Butorphanol nasal	None
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day
Acetaminophen	4g/day
Aspirin	2080mg/day
Ibuprofen	3200mg/day
Benzhydrocodone**	None

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Coverage of Off-Label Non-FDA Approved Indications

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110341
Guideline Name	Coverage of Off-Label Non-FDA Approved Indications
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols

- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehesive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus

1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.

Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**
B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**

G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3

designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed September 9, 2020.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed September 9, 2020.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2020.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed September 9, 2020.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed September 9, 2020.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/CS/6E0ED9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B9F5B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/P

FActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50. Accessed September 9, 2020.

5 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Cuvrior (trientine hydrochloride)

Prior Authorization Guideline

Guideline ID	GL-127735
Guideline Name	Cuvrior (trientine hydrochloride)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of ONE of the following:

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL (milligrams/deciliter)
- 24-hour urinary copper excretion greater than 100 mcg (micrograms)
- Liver biopsy with copper dry weight greater than 250 mcg/g (gram)
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, contraindication, or intolerance to generic penicillamine capsules

AND

4 - Prescribed by or in consultation with ONE of the following:

- Gastroenterologist
- Hepatologist

Product Name: Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

2 . Revision History

Date	Notes
7/7/2023	Updated guideline name and all criteria, indications, and auth duratio ns.

Cystaran, Cystadrops

Prior Authorization Guideline

Guideline ID	GL-77349
Guideline Name	Cystaran, Cystadrops
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2021

1 . Criteria

Product Name: Cystaran, Cystadrops	
Diagnosis	Cystinosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystinosis	

2 . Revision History

Date	Notes
11/23/2020	Added Cystadrops

Daliresp (roflumilast)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118257
Guideline Name	Daliresp (roflumilast)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe to very severe chronic obstructive pulmonary disease (COPD) [i.e., FEV1 (forced expiratory volume over 1 second) less than or equal to 50% of predicted]

AND

2 - COPD is associated with chronic bronchitis **AND** **3** - History of COPD exacerbation(s)

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to the requested therapy	

2 . Revision History

Date	Notes
12/12/2022	Updated guideline name, updated GPI and product name lists, adde d generic roflumilast, cleaned up criteria.

Daraprim

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110608
Guideline Name	Daraprim
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Daraprim, generic pyrimethamine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medical record documentation (e.g. chart notes) of one of the following:

1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

1.2 Treatment of congenital toxoplasmosis

OR

1.3 Secondary prophylaxis of toxoplasmic encephalitis

OR

1.4 ALL of the following:

1.4.1 Primary Pneumocystis pneumonia (PCP) prophylaxis in human immunodeficiency virus (HIV)-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of Pneumocystis pneumonia

AND

1.4.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.4.3 ONE of the following:

1.4.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.4.3.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

OR

1.5 ALL of the following:

1.5.1 Primary prophylaxis of toxoplasmic encephalitis

AND

1.5.2 Toxoplasma immunoglobulin G (IgG) positive

AND

1.5.3 CD4 (cluster of differentiation 4) less than or equal to 100 cells per mm3 if initiating prophylaxis or CD4 100-200 cells per mm3 if reinstituting prophylaxis

AND

1.5.4 Will be used in combination with dapsone or atovaquone

AND

1.5.5 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.5.6 ONE of the following:

1.5.6.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.5.6.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

Notes	*Consider discontinuation of primary prophylaxis if CD4 greater than 200 cells/mm3 for greater than 3 months after institution of combination antiretroviral therapy.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Daybue (trofinetide)

Prior Authorization Guideline

Guideline ID	GL-126351
Guideline Name	Daybue (trofinetide)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Daybue	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Rett syndrome

AND

2 - ONE of the following:

2.1 Submission of medical records (e.g., chart notes) confirming presence of ALL of the following clinical signs and symptoms:

2.1.1 A pattern of development, regression, then recovery or stabilization

AND

2.1.2 Partial or complete loss of purposeful hand skills, such as grasping with fingers, reaching for things, or touching things on purpose

AND

2.1.3 Partial or complete loss of spoken language

AND

2.1.4 Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing

AND

2.1.5 Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

OR

2.2 Submission of medical records (e.g., chart notes) documenting molecular genetic testing confirms mutations in the MECP2 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with ONE of the following:

- Geneticist
- Neurologist

Product Name: Daybue	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

2 . Revision History

Date	Notes
6/6/2023	New guideline

DDAVP (desmopressin) tablets

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110853
Guideline Name	DDAVP (desmopressin) tablets
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand DDAVP tablets, generic desmopressin acetate tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of central diabetes insipidus

OR

1.2 Diagnosis of polyuria and/or polydipsia following head trauma or surgery in the pituitary region **OR** **1.3** Diagnosis of primary nocturnal enuresis **AND** **2** - For Brand DDAVP ONLY: Trial and failure to generic desmopressin tablets (verified via paid pharmacy claims or submission of medical records)	
Notes	Plan setup requires use of generic desmopressin tablets before Brand DDAVP

2 . Revision History

Date	Notes
8/9/2022	C&S to match AZM 10.1.22

Declomycin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110357
Guideline Name	Declomycin
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: demeclocycline*	
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of ONE of the following:

- Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox and tick fevers caused by rickettsiae
- Respiratory tract infections caused by Mycoplasma pneumoniae
- Lymphogranuloma venereum due to Chlamydia trachomatis
- Psittacosis (Ornithosis) due to Chlamydia psittaci
- Trachoma due to Chlamydia trachomatis

- Inclusion conjunctivitis caused by Chlamydia trachomatis
- Nongonococcal urethritis in adults caused by Ureaplasma urealyticum or Chlamydia trachomatis
- Relapsing fever due to Borrelia recurrentis
- Chancroid caused by Haemophilus ducreyi
- Plague due to Yersinia pestis
- Tularemia due to Francisella tularensis
- Cholera caused by Vibrio cholerae
- Campylobacter fetus infections cause by Campylobacter fetus
- Brucellosis due to Brucella species (in conjunction with streptomycin)
- Bartonellosis due to Bartonella bacilliformis
- Granuloma inguinale caused by Calymmatobacterium granulomatis
- Infection due to Escherichia coli
- Infection due to Enterobacter aerogenes
- Infection due to Shigella species
- Infection due to Acinetobacter species
- Respiratory tract infections caused by Haemophilus influenza
- Respiratory tract and urinary tract infections caused by Klebsiella species
- Upper respiratory infections caused by Streptococcus pneumoniae
- Skin and skin structure infections caused by Staphylococcus aureus.
- Uncomplicated urethritis in men due to Neisseria gonorrhoeae, and for the treatment of other uncomplicated gonococcal infections
- Infections in women caused by Neisseria gonorrhoeae
- Syphilis caused by Treponema pallidum subspecies pallidum
- Yaws caused by Treponema pallidum subspecies pertenue
- Listeriosis due to Listeria monocytogenes
- Anthrax due to Bacillus anthracis
- Vincent's infection caused by Fusobacterium fusiforme
- Actinomycosis caused by Actinomyces israelii
- Clostridial diseases caused by Clostridium species
- Acute intestinal amebiasis, as adjunctive therapy
- Severe acne, as adjunctive therapy

OR

1.2 The medication is being prescribed by or in consultation with an Infectious Disease specialist

Notes	*Approval duration: 6 months

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Dificid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110303
Guideline Name	Dificid
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Dificid	
Approval Length	10 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile- associated diarrhea]

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to Firvanq (vancomycin) oral solution

OR

2.2 History of failure, contraindication, or intolerance to oral Vancocin (vancomycin) capsules or vancomycin oral solution (NOT Firvanq) if the prescriber provides a reason or special circumstance the patient cannot use Firvanq

OR

2.3 For continuation of prior Dificid therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Dofetilide

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110304
Guideline Name	Dofetilide
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: : Brand Tikosyn, generic dofetilide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Atrial fibrillation
- Atrial flutter

AND

2 - Patient requires ONE of the following:

- Conversion to normal sinus rhythm
- Maintenance of normal sinus rhythm

AND

3 - Verification that the patient has already started on dofetilide while in the hospital for a minimum of 3 days

AND

4 - Patient does NOT have severe renal impairment [Creatinine Clearance (CrCl) less than 20 milliliters per minute]

AND

5 - Patient does NOT have congenital or acquired long QT syndromes

AND

6 - Patient is NOT concurrently using cimetidine, hydrochlorothiazide, ketoconazole, megestrol, prochlorperazine, trimethoprim, dolutegravir or verapamil

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Dojolvi (triheptanoin)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116308
Guideline Name	Dojolvi (triheptanoin)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) showing diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) has been confirmed by at least TWO of the following:

- Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma
- Low enzyme activity in cultured fibroblasts
- One or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB

AND

2 - Not used with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to continued need of therapy

AND

2 - Not used with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

2 . Revision History

Date	Notes
11/7/2022	New guideline following FFS.

DPP-4 Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121154
Guideline Name	DPP-4 Inhibitors
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Kombiglyze XR, Janumet, Janumet XR, Januvia, Jentadueto, Onglyza, Tradjenta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 History of failure to metformin at a minimum dose of 1500 milligrams daily for 90 days

OR

2.2 Contraindication or intolerance to metformin

Product Name: alogliptin, Nesina, Kazano, alogliptin/metformin, alogliptin/pioglitazone, Oseni, Jentadueto XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 History of failure to metformin at a minimum dose of 1500 milligrams daily for 90 days

OR

2.2 Contraindication or intolerance to metformin

AND

3 - ONE of the following:

3.1 History of failure for 90 days to THREE of the following:

- Tradjenta
- Januvia
- Onglyza
- Kombiglyze XR

- Janumet
- Janumet XR
- Jentadueto

OR

3.2 Intolerance or contraindication to THREE of the following:

- Tradjenta
- Januvia
- Onglyza
- Kombiglyze XR
- Janumet
- Janumet XR
- Jentadueto

AND

4 - If the request is for a combination product (e.g., alogliptin/metformin, alogliptin/pioglitazone), the individual products have been tried and failed

2 . Revision History

Date	Notes
2/9/2023	Removed Therapeutic Duplication criteria section.

Dry Eye Disease

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110372
Guideline Name	Dry Eye Disease
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Cequa, Xiidra	
Diagnosis	Tear deficiency associated with ocular inflammation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tear deficiency associated with ocular inflammation due to ONE of the following:

- Moderate to severe keratoconjuctivitis sicca
- Moderate to severe Dry Eye Disease

AND

2 - Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g.: LASIK)

AND

3 - History of failure to at least three over-the-counter (OTC) artificial tear products (e.g.: Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP, Muro 128 2% Solution, Muro 128 5% Solution, Muro 128 5% Ointment) in the past 60 days as evidenced in the member's claim history.

AND

4 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

AND

5 - The patient has claims history indicating a minimum trial of 60 days of Restasis unless it is contraindicated.

Product Name: Cequa, Xiidra	
Diagnosis	Tear deficiency associated with ocular inflammation
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated clinically significant improvement with therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Duexis and Vimovo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110360
Guideline Name	Duexis and Vimovo
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Duexis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug) induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone)

- Concurrent use of anticoagulants (eg, warfarin, heparin)
- Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)

AND

2 - Documentation of history of failure, contraindication, or intolerance to THREE combinations of preferred NSAIDS taken with preferred H2 (histamine 2)-receptor antagonists. (Provide name and date preferred products were tried)*

AND

3 - Physician has provided rationale for needing to use fixed-dose combination therapy with Duexis instead of taking individual products in combination.

Notes	*Please reference background section for preferred products table

Product Name: Brand Vimovo, generic naproxen-esomeprazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug) induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (eg, warfarin, heparin)
- Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)

AND

2 - Documentation of history of failure, contraindication, or intolerance to THREE combinations of preferred NSAIDS taken with preferred proton pump inhibitors (PPIs). (Provide name and date preferred products were tried)*

AND **3** - Physician has provided rationale for needing to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination.
Notes | *Please reference background section for preferred products table

2 . Background

Benefit/Coverage/Program Information

Preferred Table

NSAIDS	Proton Pump Inhibitors (PPIs)	H2 (histamine 2)-receptor antagonists
Diclofenac DR (Generic Voltaren)	esomeprazole (Generic Nexium)	Famotidine (Generic Pepcid)
Diclofenac ER (Generic Voltaren ER)	lansoprazole (Generic Prevacid)	Nizatidine (Generic Axid)
Etodolac (Generic Lodine)	omeprazole (Generic Prilosec)	Ranitidine (Generic Zantac)
Etodolac ER (Generic Lodine ER)	pantoprazole sodium (Generic Protonix)	
Fenoprofen (Generic Nalfon)		
Flurbiprofen (Generic Ansaid)		
Ibuprofen		
Indomethacin (Generic Indocin)		

Ketorolac (Generic Toradol)		
Mefenamic (Generic Ponstel)		
Meloxicam (Generic Mobic)		
Nabumetone (Generic Relafen)		
Nabumetone DS (Generic Relafen DS)		
Naproxen (Generic Anaprox)		
Naproxen DR (Generic Anaprox DR)		
Naproxen EC (Generic Anaprox EC)		
Oxaprozin (Generic Daypro)		
Piroxicam (Generic Feldene)		
Sulindac (Generic Clinoril)		

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Duopa

Prior Authorization Guideline

Guideline ID	GL-75073
Guideline Name	Duopa
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2020

1 . Criteria

Product Name: Duopa	
Diagnosis	Parkinson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced Parkinson's disease

AND

2 - Patient is levodopa-responsive

AND

3 - Patient experiences disabling “off” periods for a minimum of 3 hours per day

AND

4 - Disabling “off" periods occur despite therapy with BOTH of the following:

- Oral levodopa-carbidopa
- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT [catechol-O-methyltransferase] inhibitor [entacapone, tolcapone], MAO-B [monoamine oxidase-B] inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Has undergone or has planned placement of a procedurally-placed tube

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Duopa	
Diagnosis	Parkinson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Duopa therapy

2 . Revision History

Date	Notes
10/8/2020	Annual review. Added “advanced” to the diagnosis check and the pro cedurally-placed tube placement question to align with E&I.

Dupixent (dupilumab)

Prior Authorization Guideline

Guideline ID	GL-120915
Guideline Name	Dupixent (dupilumab)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 6 months of age or older

AND

2 - Submission of documentation (e.g., chart notes) confirming ONE of the following:

2.1 BOTH of the following:

2.1.1 Diagnosis of moderate to severe chronic atopic dermatitis

AND

2.1.2 History of failure, contraindication, or intolerance to the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

OR

2.2 BOTH of the following:

2.2.1 Diagnosis of chronic atopic dermatitis that has been determined to be severe based on physician assessment

AND

2.2.2 History of failure, contraindication, or intolerance to one topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] (document drug, date of trial, and/or contraindication to medication)*

OR

2.3 Patient is currently on Dupixent therapy

AND

3 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

AND

4 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and/or contraindication to medication

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to Dupixent therapy

AND

2 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

AND

3 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of moderate-to-severe asthma

AND

2 - Patient is 6 years of age or older

AND

3 - ONE of the following:

3.1 ALL of the following:

3.1.1 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following

- Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3.1.2 Dupixent will be used in combination with ONE of the following:

3.1.2.1 ONE high-dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)] (see Table 1 in Background section)

OR

3.1.2.2 Combination therapy including BOTH of the following:

3.1.2.2.1 ONE high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)] (see Table 1 in Background section)

AND

3.1.2.2.2 ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

3.1.3 ONE of the following:

3.1.3.1 Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter within the past 6 weeks

OR

3.1.3.2 Patient is currently dependent on oral corticosteroids for the treatment of asthma

OR

3.2 Patient is currently on Dupixent therapy

AND

4 - Patient is NOT receiving Dupixent in combination with ONE of the following:

- Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g. Xolair (omalizumab)]

AND

5 - Prescribed by ONE of the following:

- Pulmonologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Dupixent is being used in combination with an inhaled corticosteroid (ICS)-containing controller medication (see Table 1 in Background section)

AND

3 - Patient is NOT receiving Dupixent in combination with ONE of the following:

- Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g. Xolair (omalizumab)]

AND

4 - Prescribed by ONE of the following:

- Pulmonologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Submission of documentation (e.g., chart notes) confirming ONE of the following:

2.1 ALL of the following:

2.1.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following:

2.1.1.1 TWO or more of the following symptoms for greater than or equal to 12 weeks duration:

- Mucopurulent discharge
- Nasal obstruction and congestion
- Decreased or absent sense of smell
- Facial pressure or pain

AND

2.1.1.2 ONE of the following:

- Evidence of inflammation on paranasal sinus examination or computed tomography (CT)
- Evidence of purulence coming from paranasal sinuses or ostiomeatal complex

AND

2.1.1.3 The presence of nasal polyps

AND

2.1.2 ONE of the following:

- Patient has required prior sino-nasal surgery
- Patient has required systemic corticosteroids in the previous 2 years

AND

2.1.3 Patient has been unable to obtain symptom relief after trial of ALL of the following agents/classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g. fluticasone, mometasone, triamcinolone, etc.)

- Antileukotriene agents (e.g. montelukast, zafirlukast, zileuton)

OR

2.2 ALL of the following:

2.2.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2.2.2 Patient is currently on Dupixent therapy

AND

3 - Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

AND

4 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

5 - Prescribed by ONE of the following:

- Otolaryngologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to Dupixent therapy

AND

2 - Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

AND

3 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

4 - Prescribed by ONE of the following:

- Otolaryngologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain)

AND

3 - Submission of documentation (e.g., chart notes, lab values) confirming patient has at least 15 intraepithelial eosinophils per high power field (HPF)

AND

4 - Other causes of esophageal eosinophilia have been excluded

AND

5 - BOTH of the following:

- Patient is at least 12 years of age
- Patient weighs at least 40 kilograms

AND

6 - Paid claims or submission of documentation (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to at least an 8-week trial of ONE of the following:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

7 - Prescribed by ONE of the following:

- Gastroenterologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to therapy as evidenced by improvement of at least ONE of the following from baseline:

- Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

AND

2 - Prescribed by ONE of the following:

- Gastroenterologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

AND

3 - Trial and failure, contraindication, or intolerance to one previous PN treatment (e.g., topical corticosteroids, topical calcineurin inhibitors [pimecrolimus, tacrolimus], topical capsaicin)

AND

4 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to therapy as evidenced by improvement of at least one of the following:

- Reduction in the number of nodular lesions from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

2 . Background

Benefit/Coverage/Program Information

Table 1: Low, medium and high daily doses of inhaled corticosteroids Adults and adolescents (12 years of age and older)

Drug	Daily dose (mcg)		
	Low	Medium	High
Beclomethasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclomethasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	N/A	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

3 . Revision History

Date	Notes
2/3/2023	Removed step through topical corticosteroid for AD indication. Updated tables in background and reference numbering throughout guideline.

Durezol

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110363
Guideline Name	Durezol
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Durezol	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to BOTH of the following:

- prednisolone 1%
- dexamethasone ophthalmic drops and/or ointment.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Ecoza (econazole)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110351
Guideline Name	Ecoza (econazole)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Ecoza, Generic econazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following:

- butenafine
- ciclopirox
- clotrimazole
- clotrimazole w/ betamethasone
- ketoconazole
- miconazole
- nystatin

- terbinafine
- tolnaftate

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Egrifta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82256
Guideline Name	Egrifta
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Egrifta SV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy	

2 . Revision History

Date	Notes

3/8/2021	Updated GPI's and product name list.

Elaprase

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-63434
Guideline Name	Elaprase
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Elaprase	
Diagnosis	Hunter syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)	

2 . Revision History

Date	Notes
3/11/2020	C&S Implementation

Elidel-Protopic

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64366
Guideline Name	Elidel-Protopic
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Elidel, generic pimecrolimus, Brand Protopic 0.03%, generic tacrolimus 0.03%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is 2 years of age or older

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid in the past 90 days

OR

2.2 Drug is being prescribed for the facial or groin area

Product Name: Brand Protopic 0.1%, generic tacrolimus 0.1%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is 16 years of age or older

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid in the past 90 days

OR

2.2 Drug is being prescribed for the facial or groin area

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Elmiron

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64367
Guideline Name	Elmiron
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Elmiron	
Diagnosis	Bladder pain or discomfort associated with interstitial cystitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a documented diagnosis of bladder pain or discomfort associated with interstitial cystitis

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Emflaza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-96700
Guideline Name	Emflaza
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name: Emflaza	
Diagnosis	Duchenne Muscular Dystrophy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy

AND

2 - Patient is 2 years of age or older

AND

3 - History of failure, contraindication, or intolerance to ONE of the following for the treatment of Duchenne muscular dystrophy:

- Prednisone
- Prednisolone

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Emflaza	
Diagnosis	Duchenne Muscular Dystrophy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician attestation that the patient has had a positive clinical response to Emflaza therapy

2 . Revision History

Date	Notes
10/14/2021	Corrected attestation spelling

Enbrel

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110675
Guideline Name	Enbrel
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Rheumatoid Arthritis (RA)

AND

2 - History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Active Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - History of failure to a 3 month trial of methotrexate at the maximally indicated dose within

the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Active Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Enbrel	
Diagnosis	Moderate to Severe Chronic Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Moderate to Severe Chronic Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Enbrel	
Diagnosis	Ankylosing spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - History of failure to two non-steroidal anti-inflammatory drugs (NSAIDs: e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

3 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Endari

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64368
Guideline Name	Endari
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of sickle cell disease
- Used to reduce acute complications of sickle cell disease

AND

2 - ONE of the following:

- Patient is using Endari with concurrent hydroxyurea therapy
- Patient is unable to take hydroxyurea due to a contraindication or intolerance

AND

3 - Patient has had 2 or more painful sickle cell crises within the past 12 months

Product Name: Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Endari therapy

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Enspryng

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135272
Guideline Name	Enspryng
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies

AND

3 - History of failure, contraindication, or intolerance to rituximab therapy

AND

4 - One of the following:

- History of one or more relapses that required rescue therapy during the previous 12 months
- History of two or more relapses that required rescue therapy during the previous 24 months

AND

5 - Prescribed by, or in consultation with, a neurologist

AND

6 - Patient is NOT receiving Enspryng in combination with any of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Complement inhibitors [e.g., Soliris (eculizumab)]
- Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]
- B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab)]

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enspryng therapy

AND

2 - Prescribed by, or in consultation with, a neurologist

AND

3 - Patient is NOT receiving Enspryng in combination with any of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Complement inhibitors [e.g., Soliris (eculizumab)]
- Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]
- B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab)]

2 . Revision History

Date	Notes
10/20/2023	Added prescriber check, trial/failure of rituximab and rescue therapy, and additional references to align with commercial med nec policy.

Entocort EC

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64369
Guideline Name	Entocort EC
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Entocort EC, generic budesonide	
Diagnosis	Chrohn's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Entocort EC is being used for the treatment of Crohn's disease	

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Entresto

Prior Authorization Guideline

Guideline ID	GL-110765
Guideline Name	Entresto
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Entresto	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - As continuation of therapy initiated during an inpatient stay

OR

2 - Both of the following:

2.1 Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic

AND

2.2 Prescribed by or in consultation with a cardiologist

OR

3 - ALL of the following:

3.1 Diagnosis of heart failure (with or without hypertension)

AND

3.2 Ejection fraction is less than or equal to 40 percent

AND

3.3 Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

AND

3.4 ONE of the following:

3.4.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following beta-blockers:

- bisoprolol
- carvedilol
- metoprolol

OR

3.4.2 Patient has a contraindication or intolerance to beta-blocker therapy

AND

3.5 Patient does not have a history of angioedema

AND

3.6 Patient will discontinue any use of concomitant ACE (angiotensin converting enzyme) Inhibitor or ARB (angiotensin II receptor blocker) before initiating treatment with Entresto*

AND

3.7 Patient is not concomitantly on aliskiren therapy

AND

3.8 Entresto is prescribed by, or in consultation with, a cardiologist

Notes	*NOTE: ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto

Product Name: Entresto	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The Entresto dose has been titrated to a dose of 97 mg (milligrams) /103 mg twice daily, or to a maximum dose as tolerated by the patient

AND **2** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Epaned

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110305
Guideline Name	Epaned
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Epaned	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is less than 8 years of age

OR

1.2 BOTH of the following:

1.2.1 ONE of the following diagnoses:

- Hypertension
- Heart failure
- Asymptomatic left ventricular dysfunction, defined as left ventricular ejection fraction less than or equal to 35%

AND

1.2.2 ONE of the following:

1.2.2.1 History of failure, contraindication, or intolerance to TWO formulary oral anti-hypertensives (e.g., angiotensin-converting enzyme (ACE) inhibitor, ACE inhibitor combination, angiotensin-receptor blockers (ARB), ARB combination, thiazide diuretic)

OR

1.2.2.2 Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to ONE of the following:

- Oral/motor difficulties
- Dysphagia

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Epinephrine Pens

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110299
Guideline Name	Epinephrine Pens
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Epinephrine Pens (Non-Mylan Manufacturer)	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - There is a shortage on Epinephrine Pens manufactured by Mylan.	
Notes	*Only approve other rebatable epinephrine autoinjectors if both the br anded EpiPen and authorized generic are on the FDA shortage list.

Product Name: Epinephrine Pens (Mylan Manufacturer)	
Approval Length	6 month(s)

Guideline Type	Quantity Limit
Approval Criteria **1** - Medication has been used or lost or the member is going on vacation.*	
Notes	Only approve other rebatable epinephrine autoinjectors if both the bra nded EpiPen and authorized generic are on the FDA shortage list

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Eplerenone

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110306
Guideline Name	Eplerenone
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Inspra, generic eplerenone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Symptomatic heart failure with reduced ejection fraction (HFrEF) after an acute myocardial infarction

OR

1.2 Hypertension

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Epsolay (benzoyl peroxide) cream

Prior Authorization Guideline

Guideline ID	GL-110300
Guideline Name	Epsolay (benzoyl peroxide) cream
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Epsolay	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rosacea

AND

2 - Patient has inflammatory lesions

AND **3** - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to one preferred topical product for rosacea (e.g., metronidazole cream/gel/lotion) (verified via paid pharmacy claims)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Erythropoietic Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129552
Guideline Name	Erythropoietic Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Aranesp, Epogen, Procrit, Mircera, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Hematocrit is less than 30% at initiation of therapy

AND

3 - ONE of the following:

3.1 Patient is on dialysis

OR

3.2 ALL of the following:

3.2.1 Patient is NOT on dialysis

AND

3.2.2 The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

3.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

4 - If the request is for Mircera; claims history indicates either Aranesp, Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Aranesp, Epogen, Procrit, Mircera, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is on dialysis

AND

2.1.2 Most recent or average Hct (hematocrit) over 3 months is 33% or less [Hgb (hemaglobin) 11 g/dL (grams/deciliter) or less]

OR

2.2 ALL of the following:

2.2.1 Patient is NOT on dialysis

AND

2.2.2 Most recent or average (avg) Hct over 3 months is 30% or less (Hgb 10 g/dL or less)

AND

2.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

OR

2.3 BOTH of the following:

2.3.1 Request is for a pediatric patient

AND

2.3.2 Most recent or average Hct over 3 months is 36% or less (Hgb 12 g/dL or less)

AND

3 - ONE of the following:

3.1 Decrease in the need for blood transfusion

OR

3.2 Hgb increased greater than or equal to 1 g/dL from pre-treatment level

AND

4 - If the request is for Mircera; claims history indicates either Aranesp, Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Zidovudine Treatment in HIV-Infected Patients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week

AND

2 - Endogenous serum erythropoietin level is less than or equal to 500 milliunits per milliliter

AND

3 - Hematocrit is less than 30% at initiation of therapy

Product Name: Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Cancer Chemotherapy
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit less than 30% at initiation of therapy

AND

2 - There is a minimum of two additional months of planned chemotherapy

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Perioperative hematocrit is greater than 30% and less than or equal to 39%

AND

2 - Patient is at high risk for blood loss during surgery

AND

3 - Patient is unable or unwilling to donate autologous blood

AND

4 - Surgery procedure is elective, non-cardiac, and non-vascular

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic disease (MDS)

AND

2 - ONE of the following:

- Serum erythropoietin level less than or equal to 500 milliunits per milliliter
- Hematocrit is less than or equal to 30% at the initiation of therapy

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Disease

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Hematocrit remains less than 36%

OR

1.2 Patient has demonstrated a response to therapy

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C virus (HCV) infection

AND

2 - Patient is receiving ribavirin and interferon therapy

AND

3 - Hematocrit is less than or equal to 30% at initiation of therapy

Product Name: Epogen, Procrit, Retacrit*	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Hematocrit remains less than 36%

OR

1.2 Patient has demonstrated a response to therapy

Notes	*Authorization will be issued for 12 months or if patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy.

Product Name: Aranesp, Epogen, Mircera, Procrit, Retacrit*	
Diagnosis	Erythropoietin Stimulating Agents - Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

AND

2 - Requests for coverage in patients with hemoglobin (Hgb) greater than 10 grams per deciliter or hematocrit (Hct) greater than 30% will not be approved

AND

3 - If the request is for Mircera; claims history indicates either Aranesp, Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling	
Notes	*If the request is deemed medically necessary, the authorization will b e issued for requested length of therapy.

2 . Revision History

Date	Notes
8/11/2023	Removed embedded step for Procrit.

Esbriet, Ofev

Prior Authorization Guideline

Guideline ID	GL-116688
Guideline Name	Esbriet, Ofev
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Brand Esbriet, generic pirfenidone, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by ALL of the following criteria:

1.1 Exclusion of other known causes of interstitial lung disease (e.g. domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by the following:

- ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis)

AND

1.2 ONE of the following:

1.2.1 In patients NOT subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF

AND

2 - The agent is not being used in combination with Esbriet or Ofev

AND

3 - The prescriber is a pulmonologist

AND

4 - If requesting generic pirfenidone, patient has tried and failed, or has intolerance to Brand Esbriet

Product Name: Brand Esbriet, generic pirfenidone, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - The agent is not being used in combination with Esbriet or Ofev

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis (SSc) - associated interstitial lung disease as documented by ALL of the following:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)

- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on high-resolution computed tomography (HRCT), involving at least 10 percent of the lungs

AND

2 - The agent is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Chronic fibrosing interstitial lung disease with a progressive phenotype
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype as documented by BOTH of the following criteria:

1.1 Presence of fibrotic ILD as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10 percent of the lungs

AND

1.2 Patient is presenting with clinical signs of progression as defined by ONE of the following in the previous 24 months:

1.2.1 Forced vital capacity (FVC) decline of greater than 10 percent

OR

1.2.2 TWO of the following:

- FVC decline of greater than or equal to 5 percent, but less than 10 percent
- Patient is experiencing worsening respiratory symptoms
- Patient is exhibiting increasing extent of fibrotic changes on chest imaging

AND

2 - The agent is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease, Chronic fibrosing interstitial lung disease with a progressive phenotype
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND **2** - Ofev is not being used in combination with Esbriet **AND** **3** - The prescriber is a pulmonologist

2 . Revision History

Date	Notes
11/7/2022	Added pirfenidone as NP target

Estrogens

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110307
Guideline Name	Estrogens
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Femring	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause

OR

2 - Diagnosis of moderate to severe vulvar and vaginal atrophy due to menopause

Product Name: Premarin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atrophic vaginitis and kraurosis vulvae

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Eucrisa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118339
Guideline Name	Eucrisa
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Eucrisa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide]

AND

1.2 ONE of the following:

1.2.1 Patient is less than 2 years of age

OR

1.2.2 Patient is greater than or equal to 2 years of age and has history of failure, contraindication, or intolerance to ONE topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

2 . Revision History

Date	Notes
12/13/2022	Updated guideline type.

Evrysdi (risdiplam)

Prior Authorization Guideline

Guideline ID	GL-116058
Guideline Name	Evrysdi (risdiplam)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

2.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.2 Compound heterozygous mutation of SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

5 - Patient is not receiving concomitant chronic survival motor neuron (SMN)-modifying therapy [e.g., Spinraza (nusinersen)]

AND

6 - Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

7 - Submission of medical records (e.g., chart notes, laboratory values) documenting the baseline assessment of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability (baseline motor function analysis could include

assessments evaluated prior to receipt of previous chronic SMN-modifying therapy if transitioning therapy)*:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test
- Motor Function Measure 32 (MFM-32) Scale

AND

8 - Prescribed by a neurologist with expertise in the treatment of SMA

Notes	*Baseline assessments for patients less than 2 months of age request ing Evrysdi are not necessary in order not to delay access to initial the rapy in recently diagnosed infants. Initial assessments shortly post-the rapy can serve as baseline with respect to efficacy reauthorization ass essment.

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response to Evrysdi compared to pretreatment baseline status [inclusive of baseline assessments prior to receipt of previous chronic survival motor neuron (SMN)-modifying therapy] as demonstrated by at least ONE of the following exams:

1.1 Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) with ONE of the following:

1.1.1 Improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline

OR

1.1.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.2 Hammersmith Infant Neurological Exam Part 2 (HINE-2) with ONE of the following:

1.2.1 Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick

OR

1.2.2 Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp

OR

1.2.3 The patient exhibited improvement, or maintenance of previous improvement, in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)

OR

1.2.4 Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so

OR

1.3 Hammersmith Functional Motor Scale Expanded (HFMSE) with ONE of the following:

1.3.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.3.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.4 Upper Limb Module (ULM) with ONE of the following:

1.4.1 Improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline

OR

1.4.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.5 Motor Function Measure 32 (MFM-32) with ONE of the following:

1.5.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.5.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

AND

3 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

4 - Patient is not receiving concomitant chronic SMN-modifying therapy [e.g., Spinraza (nusinersen)]

AND

5 - Patient has not previously received gene replacement therapy for the treatment of spinal muscular atrophy (SMA) [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

6 - Prescribed by a neurologist with expertise in the treatment of SMA

2 . Revision History

Date	Notes
10/24/2022	Updated GL name. Removed age requirement and updated note.

Exkivity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118603
Guideline Name	Exkivity
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is locally advanced or metastatic

AND

3 - Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive

AND

4 - Subsequent therapy for disease that has progressed on or after platinum-based chemotherapy

Product Name: Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Exkivity therapy

Product Name: Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Exkivity therapy

Exondys

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116689
Guideline Name	Exondys
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Exondys	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating Duchenne Muscular Dystrophy

AND

4 - Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

5 - If ambulatory, patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

Product Name: Exondys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has been on therapy for less than 12 months and all of the following:

1.1.1 Patient is tolerating therapy

AND

1.1.2 Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

1.1.3 Prescribed by or in consultation with a neurologist who has experience treating Duchenne Muscular Dystrophy

AND

1.1.4 If ambulatory, patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

OR

1.2 Patient has been on therapy for 12 months or more and all of the following:

1.2.1 Patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients)

AND

1.2.2 Patient is tolerating therapy

AND

1.2.3 Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

1.2.4 Prescribed by or in consultation with a neurologist who has experience treating Duchenne Muscular Dystrophy

AND

1.2.5 If ambulatory, patient's condition has been evaluated via the 6-minute walk test

(6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

2 . Revision History

Date	Notes
11/7/2022	Removed age and ambulatory requirements

Ezallor Sprinkle (rosuvastatin)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132851
Guideline Name	Ezallor Sprinkle (rosuvastatin)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Ezallor	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Patient is less than 10 years of age

AND

1.1.2 Prescribed by or in consultation with a cardiologist

OR

1.2 BOTH of the following:

1.2.1 Medication is being used for ONE of the following:

1.2.1.1 To reduce the risk of ONE of the following:

- Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
- MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD
- Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD

OR

1.2.1.2 As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in ONE of the following:

- Adults with primary hyperlipidemia
- Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)

OR

1.2.1.3 As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with homozygous familial hypercholesterolemia (HoFH)

OR

1.2.1.4 As an adjunct to diet for the treatment of adults with ONE of the following:

- Primary dysbetalipoproteinemia
- Hypertriglyceridemia

AND

1.2.2 ONE of the following:

1.2.2.1 Trial and failure, contraindication, or intolerance to generic rosuvastatin tablets (verified via paid pharmacy claims or submitted chart notes)

OR

1.2.2.2 Patient is unable to swallow oral tablets

2 . Revision History

Date	Notes
9/11/2023	New Program

Fabry Disease Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129615
Guideline Name	Fabry Disease Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Fabrazyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient is 2 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming ONE of the following:

3.1 Detection of pathogenic mutations in the GLA gene by molecular genetic testing

OR

3.2 Deficiency in alpha-galactosidase A (alpha-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)

OR

3.3 Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

4 - Will not be used in combination with Galafold (migalastat)

Product Name: Fabrazyme	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes

8/9/2023	Updated guideline name, updated all criteria.

Fasenra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110677
Guideline Name	Fasenra
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Fasenra Pen	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80 percent predicted [in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting ONE of the following:

3.1 Asthma is an eosinophilic phenotype as defined by a baseline (pre-benralizumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter within the past 6 weeks

OR

3.2 Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

AND

4 - Fasenra will be used in combination with ONE of the following:

4.1 One high dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

4.2 Combination therapy including BOTH of the following:

4.2.1 One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

4.2.2 One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

5 - Patient is not receiving Fasenra in combination with one of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

6 - Prescribed by one of the following:

- Pulmonologist
- Allergist

- Immunologist

Product Name: Fasenra Pen	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing controller medication

AND

3 - Patient is not receiving Fasenra in combination with one of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

4 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Fecal Microbiota Agents

Prior Authorization Guideline

Guideline ID	GL-129652
Guideline Name	Fecal Microbiota Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Vowst	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of recurrent clostridioides difficile infection (CDI) as defined by BOTH of the following:

1.1 Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days

AND

1.2 A positive stool test for C. difficile toxin or toxigenic C. difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of two or more recurrent episodes of CDI within 12 months

AND

4 - Submission of medical records (e.g., chart notes) confirming ALL of the following:

4.1 Patient has completed at least 10 consecutive days of ONE of the following antibiotic therapies 2-4 days prior to initiating Vowst*:

- Oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst

AND

4.3 Previous episode of CDI is under control [e.g., less than 3 unformed/loose (i.e., Bristol Stool Scale type 6-7) stools/day for 2 consecutive days]

AND

5 - Prescribed by or in consultation with ONE of the following: • Gastroenterologist • Infectious disease specialist	
Notes	*Trial requirements may be verified via paid pharmacy claims or submission of medical records/chart notes.

2 . Revision History

Date	Notes
8/9/2023	New guideline.

Fentanyl IR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110331
Guideline Name	Fentanyl IR
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Fentanyl citrate lozenges (generic Actiq)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

Product Name: Abstral, Brand Actiq, Brand Fentora, generic fentanyl citrate buccal tablet, Lazanda, Subsys

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

AND

5 - History of failure, contraindication, or intolerance to Fentanyl citrate lozenges (generic Actiq) [Document date of trial]

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Fexmid (cyclobenzaprine 7.5mg)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110308
Guideline Name	Fexmid (cyclobenzaprine 7.5mg)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Fexmid 7.5mg, generic cyclobenzaprine 7.5mg	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of muscle spasm associated with acute, painful musculoskeletal conditions

AND

2 - Reason or special circumstance the patient cannot use cyclobenzaprine 5 milligram (mg) or 10mg tablet

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Filspari (sparsentan)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125298
Guideline Name	Filspari (sparsentan)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Filspari	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g (gram), or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

AND

3 - Used to reduce proteinuria

AND

4 - Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 30 mL/min/1.73 m2 (milliliters/minute/1.73 square meters)

AND

5 - Submission of medical records (e.g., chart notes) demonstrating patient has been on a minimum 90-day trial of a maximally tolerated dose of one of the following (paid pharmacy claims may be used to confirm appropriate trial):

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

AND

6 - Medication will not be used in combination with any of the following:

- Angiotensin receptor blockers
- Endothelin receptor antagonists (ERAs) (e.g., ambrisentan, bosentan, Opsumit)
- Aliskiren

AND

7 - Prescribed by or in consultation with a nephrologist

Product Name: Filspari	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a positive clinical response to therapy as demonstrated by a decrease in urine protein-to-creatinine ratio (UPCR) from baseline

AND

2 - Medication is not taken in combination with any of the following:

- Angiotensin receptor blockers
- Endothelin receptor antagonists (ERAs) (e.g., ambrisentan, bosentan, Opsumit)
- Aliskiren

2 . Revision History

Date	Notes
5/3/2023	New guideline

Firdapse

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116659
Guideline Name	Firdapse
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Firdapse	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g.,Ampyra (dalfampridine), Ruzurgi (amiframpridine)]

AND

3 - Patient is 6 years of age or older

Product Name: Firdapse	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Firdapse therapy

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g.,Ampyra (dalfampridine), Ruzurgi (amifampridine)]

2 . Revision History

Date	Notes
11/7/2022	Added age requirement.

Flucytosine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110332
Guideline Name	Flucytosine
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Ancobon, generic flucytosine	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of septicemia, endocarditis or a urinary system infection caused by Candida species

OR

1.2 Diagnosis of meningitis or a pulmonary infection caused by Cryptococcus species **AND** **2** - If the patient is being treated for a systemic infection, flucytosine is being used in combination with amphotericin B

Product Name: Brand Ancobon, generic flucytosine*	
Diagnosis	Infectious Diseases Society of America (IDSA) Recommended Regimens
Guideline Type	Prior Authorization
Approval Criteria **1** - The medication is being prescribed by or in consultation with an infectious disease specialist.	
Notes	*Approval duration based on provider recommended treatment duratio ns, up to 12 months.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Forteo, Prolia, Teriparatide, Tymlos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120930
Guideline Name	Forteo, Prolia, Teriparatide, Tymlos
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Prolia, Forteo	
Diagnosis	Patients with osteoporosis at high risk for fracture
Approval Length	24 Months**
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteoporosis

AND

2 - ONE of the following:

2.1 Bone Mineral Density (BMD) T-score less than or equal to -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [NOTE: Provider must submit patient specific BMD T-score]

OR

2.2 BOTH of the following:

2.2.1 BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [NOTE: Provider must submit patient specific BMD T-score]

AND

2.2.2 ONE of the following:

2.2.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.2.2.2 History of failure, contraindication, or intolerance to ONE conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)*

OR

2.3 ALL of the following:

2.3.1 BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [NOTE: Provider must submit patient specific BMD T-score]

AND

2.3.2 ONE of the following:

2.3.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.3.2.2 ONE of the following Fracture Risk Assessment Tool (FRAX) 10-year fracture probabilities:

- Major osteoporotic fracture at 20 percent or more
- Hip fracture at 3 percent or more

AND

2.3.3 History of failure, contraindication, or intolerance to one conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)*

AND

3 - Treatment duration has not exceeded a total of 24 months** of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial **Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Forteo, Tymlos) in the patient's lifetime

Product Name: Brand Teriparatide, Tymlos

Diagnosis	Patients with osteoporosis at high risk for fracture
Approval Length	24 Months **
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteoporosis

AND

2 - ONE of the following:

2.1 Bone Mineral Density (BMD) T-score less than or equal to -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [NOTE: Provider must submit patient specific BMD T-score]

OR

2.2 BOTH of the following:

2.2.1 BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [NOTE: Provider must submit patient specific BMD T-score]

AND

2.2.2 ONE of the following:

2.2.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.2.2.2 History of failure, contraindication, or intolerance to ALL of the following (Document drug, date, and duration of trial

- bisphosphonate (e.g. alendronate, ibandronate)
- selective estrogen receptor modulator (SERM) (e.g raloxifene)
- Prolia (denosumab)
- Forteo (teriparatide)

OR

2.3 ALL of the following:

2.3.1 BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

AND

2.3.2 ONE of the following

2.3.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.3.2.2 ONE of the following Fracture Risk Assessment Tool (FRAX) 10-year fracture probabilities:

- Major osteoporotic fracture at 20 percent or more
- Hip fracture at 3 percent or more

AND

2.3.3 History of failure, contraindication, or intolerance to ALL of the following (Document drug, date, and duration of trial)

- bisphosphonate (e.g. alendronate, ibandronate)
- selective estrogen receptor modulator (SERM) (e.g raloxifene)
- Prolia (denosumab)
- Forteo (teriparatide)

AND

3 - Treatment duration has not exceeded a total of 24 months** of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial **Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Forteo, Tymlos) in the patient's lifetime

2 . Revision History

Date	Notes
2/9/2023	Added Tymlos, Prolia and Teriparatide as targets. Updated criteria. Renamed guideline.

Fotivda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127462
Guideline Name	Fotivda
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is refractory

AND

3 - Patient has received two or more prior systemic therapies

Product Name: Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Fotivda therapy

Product Name: Fotivda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Fotivda	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fotivda therapy

2 . Revision History

Date	Notes
7/3/2023	Updated GPI

Furoscix (furosemide injection)

Prior Authorization Guideline

Guideline ID	GL-120985
Guideline Name	Furoscix (furosemide injection)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Furoscix	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of chronic heart failure

AND

2 - Patient has New York Heart Association (NYHA) Class II or III

AND **3** - Patient is currently on maintenance oral diuretic therapy (e.g., bumetanide, furosemide, torsemide) **AND** **4** - Provider attests that patient will be closely monitored for fluid, electrolyte, and metabolic abnormalities throughout therapy (e.g., hypokalemia, hypovolemia, hyponatremia)

2 . Revision History

Date	Notes
2/9/2023	New guideline.

Galafold

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64466
Guideline Name	Galafold
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

AND

3 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Galafold therapy

AND

2 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Gattex (teduglutide)

Prior Authorization Guideline

Guideline ID	GL-136004
Guideline Name	Gattex (teduglutide)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Gattex	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming all of the following:

1.1 Diagnosis of short bowel syndrome

AND

1.2 Patient is 1 year of age and older

AND

1.3 Documentation that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months

AND

2 - Prescribed by or in consultation with a gastroenterologist

Product Name: Gattex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on Gattex therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
11/7/2023	Updated guideline name and criteria to match AZM

Gaucher's Disease Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-81442
Guideline Name	Gaucher's Disease Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name: Cerdelga	
Diagnosis	Type 1 Gaucher’s disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher’s disease

AND

2 - Patient is one of the following as detected by a Food and Drug Administration (FDA)-cleared test:

- CYP2D6 extensive metabolizer,
- CYP2D6 intermediate metabolizer
- CYP2D6 poor metabolizer

Product Name: Cerezyme	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher's disease that results in one or more of the following conditions:

- Anemia
- Thrombocytopenia
- Bone disease
- Hepatomegaly or splenomegaly

Product Name: Vpriv, Elelyso	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher's disease

Product Name: Brand Zavesca, generic miglustat	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher's disease

AND

2 - If the request is for generic miglustat, there is a reason or special circumstance why the patient cannot use brand Zavesca

Product Name: Cerdelga, Cerezyme, Elelyso, Vpriv, Brand Zavesca, generic miglustat	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
2/23/2021	Added step through brand Zavesca for generic requests to match AZ state PDL.

Gleevec

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110752
Guideline Name	Gleevec
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Generic imatinib	
Diagnosis	Chronic myelogenous or myeloid leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myelogenous or myeloid leukemia (CML)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS) or Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic disease or myeloproliferative disease (MDS/MPD)

AND

2 - ONE of the following:

- Disease is associated with 5q31-33 (gene) translocations

- Disease is associated with platelet-derived growth factor receptor (PDGRF) beta gene re-arrangements

AND

3 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - ONE of the following:

- Patient is without the D816V c-Kit (gene)mutation
- c-Kit mutational status unknown

AND

3 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES) / Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of at least ONE of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dermatofibrosarcoma protuberans (DFSP)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gastrointestinal stromal tumors (GIST)
- Desmoid tumors / aggressive fibromatosis
- Pigmented villonodular synovitis (PVNS) or tenosynovial giant cell tumor (TGCT)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec

Product Name: Generic imatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma:

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Patient has C-KIT (gene) mutation

AND

3 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	AIDS-Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - Not used as first line therapy

AND

4 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is currently being treated with systemic corticosteroids

AND

3 - Patient had no response to first-line therapy options

AND

4 - If the request is for generic imatinib, there is a reason or special circumstance the patient cannot use brand Gleevec

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - One of the following:

- FIP1L1-PDGFRA rearrangement
- PDGFRB rearrangement
- ABL1 rearrangement

AND

3 - If the request is for generic imatinib, there is a reason or special circumstance the patient cannot use brand Gleevec

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	All Indications except NCCN
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gleevec therapy

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Gleevec therapy	

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Global Quantity Limits

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-101678
Guideline Name	Global Quantity Limits
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/15/2020

1 . Criteria

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review (General)
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for an FDA-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review for the treatment of gender dysphoria*
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

Notes	* If the above criteria are not met, then refer for clinical review by an a ppropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Monthly prescription limit review for migraine therapy, benzodiazepines, or muscle relaxants
Approval Length	1 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month.

Notes	*If deemed medically necessary, longer authorization duration is perm itted

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Topical products exceeding the allowable package size per fill OR the allowable quantity per month
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The physician attests that a larger quantity is needed for treatment of a larger surface area.

2 . Revision History

Date	Notes
1/10/2022	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

GLP-1 Agonists

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121153
Guideline Name	GLP-1 Agonists
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Byetta, Trulicity, Victoza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

1.1 Diagnosis of type 2 diabetes mellitus

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - Patient is 10 years of age or older

AND

3 - Drug is not solely being used for weight loss

Product Name: Adlyxin, Bydureon BCise, Mounjaro, Ozempic	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

1.1 Diagnosis of type 2 diabetes mellitus

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - History of a 90 day trial per patient's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the following (verified via paid pharmacy claims or submission of medical records):

- Byetta
- Victoza
- Trulicity

AND

3 - ONE of the following:

3.1 If the request is for Bydureon BCise, patient is 10 years of age or older

OR

3.2 If the request is for Adlyxin, Mounjaro, or Ozempic, patient is 18 years of age or older

AND

4 - Drug is not solely being used for weight loss

Product Name: Rybelsus	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

1.1 Diagnosis of type 2 diabetes mellitus

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 History of a 90 day trial per patient's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the following (verified via paid pharmacy claims or submission of medical records):

- Byetta
- Victoza
- Trulicity

OR

2.2 BOTH of the following:

2.2.1 The patient is unable to self-inject due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

2.2.2 History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana
- Invokamet
- Synjardy
- Xigduo XR

AND

3 - Patient is 18 years of age or older

AND **4** - Drug is not solely being used for weight loss

2 . Revision History

Date	Notes
2/9/2023	Removed therapeutic duplication criteria section.

Glycopyrrolate Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-111477
Guideline Name	Glycopyrrolate Products
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Dartisla ODT, Brand Cuvposa, Brand Robinul, Brand Robinul Forte	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to generic glycopyrrolate tablets or oral solution (verified via pharmacy paid claims or submission of medical records/chart notes)

Gonadotropin-Releasing Hormone Agonists

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126355
Guideline Name	Gonadotropin-Releasing Hormone Agonists
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: leuprolide acetate inj kit 5 mg/mL, Lupron Depot Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central precocious puberty (idiopathic or neurogenic)

AND

2 - Onset of secondary sexual characteristics in one of the following:

2.1 Females less than or equal to 8 years of age

OR

2.2 Males less than or equal to 9 years of age

AND

3 - Confirmation of diagnosis as defined by one of the following:

3.1 Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)

OR

3.2 A pubertal luteinizing hormone response to a gonadotropin releasing hormone (GnRH) stimulation test

OR

3.3 Bone age advanced one year beyond the chronological age

AND

4 - If the request is for Triptodur or Fensolvi, history of failure, contraindication, or intolerance to Lupron-Depot Ped

Product Name: leuprolide acetate inj kit 5 mg/mL, Lupron Depot Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving therapy for central precocious puberty

AND

2 - Documentation of positive clinical response to therapy

AND

3 - Patient is ONE of the following (younger than the appropriate time point for the onset of puberty):

3.1 Female younger than 11 years of age

OR

3.2 Male younger than 12 years of age

Product Name: Lupaneta Pack, Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to both of the following:

2.1.1 Oral contraceptives or depot medroxyprogesterone (e.g., Depo- Provera)

AND

2.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs)

OR

2.2 Patient has had surgical ablation to prevent recurrence

AND

3 - If the request is for Lupaneta Pack, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupaneta Pack, Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - Recurrence of symptoms following an initial course of therapy

AND

3 - Concurrently to be used with add-back therapy (e.g., progestin, estrogen, or bone sparing agents)

Product Name: Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Uterine Leiomyomata (Fibroids)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 For the treatment of uterine leiomyomata-related anemia

AND

1.1.2 Patient did not respond to iron therapy of 1 month duration

AND

1.1.3 For use prior to surgery

OR

1.2 For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Gender dysphoria in adolescents
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

2 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

3 - Patient has experienced puberty development to at least Tanner stage 2

AND

4 - One of the following laboratory tests, based upon the laboratory reference range, confirming:

- Pubertal levels of estradiol in females
- Pubertal levels of testosterone in males
- Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)
- A pubertal luteinizing hormone response to a gonadotropin-releasing hormone (GnRH) stimulation test

AND

5 - A letter from the prescriber and/or formal documentation stating all of the following:

5.1 Patient has experienced pubertal changes that have resulted in an increase of their gender dysphoria that has significantly impaired psychological or social functioning

AND

5.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

5.3 Both of the following:

5.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

5.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

5.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

AND

6 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Gender dysphoria in adolescents
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Documentation (within the last 6 months) of appropriate luteinizing hormone (LH) suppression
- Change in dosing

AND

2 - Documented diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

3 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

4 - A letter from the prescriber and/or formal documentation stating all of the following:

4.1 Patient continues to meet their individual goals of therapy for gender dysphoria

AND

4.2 Patient continues to have a strong affinity for the desired (opposite of natal) gender

AND

4.3 Discontinuation of treatment and subsequent pubertal development would interfere with or impair psychological functioning and well-being

AND

4.4 Coexisting psychiatric and medical comorbidities or social problems that may interfere with treatment continue to be addressed or removed

AND

4.5 Both of the following:

4.5.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

4.5.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

4.6 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

2 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

3 - Gonads (i.e., testes, ovaries) have not been removed and are functional (e.g., hormone producing)

AND

4 - Patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

5 - Inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

6 - A letter from the prescriber and/or formal documentation stating all of the following:

6.1 Transgender patient has identified goals of gender-affirming hormone therapy

AND

6.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

6.3 Both of the following:

6.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

6.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

6.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

AND

7 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Documentation (within the last 6 months) of appropriate luteinizing hormone (LH) suppression
- Change in dosing

AND

2 - Documented diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

3 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

4 - Gonads (i.e., testes, ovaries) are intact

AND

5 - Patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

6 - Inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

7 - A letter from the prescriber and/or formal documentation stating all of the following:

7.1 Transgender patient continues to meet goals of gender-affirming hormone therapy

AND

7.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment continue to be addressed or removed

AND

7.3 Both of the following:

7.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

7.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

7.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Product Name: Lupron Depot, Lupron Depot Ped, Lupaneta Pack, Triptodur, leuprolide acetate inj kit 5 mg/mL, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For use in pre-menopausal women

AND

2 - Patient is receiving a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

AND

3 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot.

Product Name: Lupron Depot, Lupron Depot Ped, Lupaneta Pack, Triptodur, leuprolide acetate inj kit 5 mg/mL, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving gonadotropin-releasing hormone (GnRH) analog therapy for the purpose of fertility preservation

AND

2 - Patient continues to receive a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

Product Name: Lupron Depot 7.5 mg, 22.5 mg, 30 mg and 45 mg, leuprolide acetate inj kit 5 mg/mL, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Advanced or Metastatic Prostate Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

2 . Revision History

Date	Notes
6/6/2023	Added new GPI for Lupron Depot Ped.

Gralise, Horizant

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126370
Guideline Name	Gralise, Horizant
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Gralise	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postherpetic neuralgia (PHN)

AND

2 - Trial and failure or intolerance to generic gabapentin

Product Name: Horizant	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of postherpetic neuralgia (PHN)

OR

1.2 Diagnosis of restless legs syndrome

2 . Revision History

Date	Notes
6/6/2023	Updated GPI's. Added new strengths of Gralise, and added step thro ugh immediate release gabapentin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137427
Guideline Name	Growth Hormone, Growth Stimulating Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Increlex, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Idiopathic Short Stature (ISS)
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for coverage for diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved	
Notes	Approval Length: N/A - Requests for Idiopathic Short Stature (ISS) sh ould not be approved. Deny as a benefit exclusion.

Product Name: Humatrope, Saizen, Saizenprep, Serostim, Zorbtive, Nutropin AQ Nuspin, Sogroya, Ngenla, Skytrofa	
Diagnosis	Non-Preferred Review
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried and failed ALL preferred products listed below:

- Brand Genotropin/Genotropin Miniquick
- Brand Norditropin Flexpro
- Brand Omnitrope
- Brand Zomacton

Notes	Authorization duration should match the clinical criteria section for the indication that the patient has.

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)*
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following:

1.1.1 All of the following:

- Infant is less than 4 months of age
- Infant has growth deficiency
- Prescribed by an endocrinologist

OR

1.1.2 BOTH of the following:

- History of neonatal hypoglycemia associated with pituitary disease
- Prescribed by an endocrinologist

OR

1.1.3 BOTH of the following:

- Diagnosis of panhypopituitarism
- Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of pediatric growth hormone (GH) deficiency as confirmed by ONE of the following:

1.2.1.1 Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is greater than 2.0 standard deviations (SD) below midparental height utilizing age and gender growth charts related to height

OR

1.2.1.2 Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height

OR

1.2.1.3 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.4 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 ONE of the following:

1.2.2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.2.3.1 BOTH of the following:

1.2.3.1.1 Patient has undergone TWO of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa
- Growth hormone releasing hormone

AND

1.2.3.1.2 BOTH GH response values are less than 10 micrograms per liter

OR

1.2.3.2 BOTH of the following:

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 ONE of the following is below the age and gender adjusted normal range as provided by the physician's lab:

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

1.2.4 ONE of the following:

1.2.4.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

1.2.4.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

1.2.5 Prescribed by an endocrinologist

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency.

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:**

- Previous height and date obtained
- Current height and date obtained

AND

2 - BOTH of the following:**

- Expected adult height not attained
- Documentation of expected adult height goal (e.g., genetic potential)

AND

3 - Calculated height (growth) velocity over the past 12 months

AND

4 - ONE of the following:

4.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

4.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

5 - ONE of the following:

5.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

5.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

6 - Prescribed by an endocrinologist

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency. **Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome

AND

2 - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following criteria:

1.1 BOTH of the following:

1.1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

AND

1.1.2 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 BOTH of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

1.2.3 Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small for gestational age (SGA) based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by documentation that ONE of the following is below the third percentile for gestational age [more than 2 standard deviations (SD) below population mean]:

- Birth weight
- Birth length

AND

2 - Documentation that height remains less than or equal to the third percentile (more than 2 SD below population mean)

AND

3 - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height, and goal expected adult height will be required for renewal.

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with ONE of the following:

1.1 BOTH of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 BOTH of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 ONE of the following:

1.2.2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Height is below the fifth percentile on growth charts for age and gender

AND

3 - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short-stature homeobox (SHOX) gene deficiency as confirmed by genetic testing

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 BOTH of the following:

- Patient is female

- Bone age less than 14 years

AND

3 - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height, and goal expected adult height will be required for renewal.

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Notes	*Documentation of previous height, current height, and goal expected adult height will be required for renewal.

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult growth hormone deficiency (GHD) as a result of ONE of the following:

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 BOTH of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has undergone ONE of the following GH (growth hormone) stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- Glucagon
- ARG

AND

2.1.2 ONE of the following peak GH values:

2.1.2.1 ITT less than or equal to 5 micrograms per liter

OR

2.1.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter (mcg/L) if body mass index (BMI) is less than 25 kilograms per square meter (kg/m^2)
- Less than or equal to 8 mcg/L if BMI is greater than or equal to 25 and less than 30 kg/m^2
- Less than or equal to 4 mcg/L if BMI is greater than or equal to 30 kg/m^2

OR

2.1.2.3 Glucagon less than or equal to 3 mcg/L

OR

2.1.2.4 ARG less than or equal to 0.4 mcg/L

OR

2.2 BOTH of the following:

2.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting deficiency of THREE of the following anterior pituitary hormones:

- Prolactin
- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

2.2.2 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - ONE of the following:

3.1 Diagnosis of panhypopituitarism

OR

3.2 Other diagnosis and NOT used in combination with any of the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

4 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

5 - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of Insulin-like Growth Factor 1 (IGF-1)/Somatomedin C level within the past 12 months

AND

2 - ONE of the following:

2.1 Diagnosis of panhypopituitarism

OR

2.2 Other diagnosis and NOT used in combination with any of the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

3 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

4 - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

2 - Documentation of ONE of the following:

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

3.1 BOTH of the following:

3.1.1 Documentation of high risk of growth hormone (GH) deficiency due to GH deficiency in childhood from ONE of the following:

3.1.1.1 Embryopathic/congenital defects

OR

3.1.1.2 Genetic mutations

OR

3.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

3.1.1.4 Panhypopituitarism

OR

3.1.1.5 Deficiency of THREE of the following anterior pituitary hormones:

- ACTH (adrenocorticotropic hormone)

- TSH (thyroid stimulating hormone)
- Prolactin
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

3.1.2 ONE of the following:

3.1.2.1 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

3.1.2.2 ALL of the following:

3.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

3.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

3.1.2.2.3 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- ARG
- Glucagon

AND

3.1.2.2.4 ONE of the following peak GH values:

3.1.2.2.4.1 ITT less than or equal to 5 micrograms per liter (mcg/L)

OR

3.1.2.2.4.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 mcg/L if body mass index (BMI) is less than 25 kilograms per square meter (kg/m^2)
- Less than or equal to 8 mcg/L if BMI is greater than or equal to 25 and less than 30 kg/m^2
- Less than or equal to 4 mcg/L if BMI is greater than or equal to 30 kg/m^2

OR

3.1.2.2.4.3 Glucagon less than or equal to 3 mcg/L

OR

3.1.2.2.4.4 ARG less than or equal to 0.4 mcg/L

OR

3.2 ALL of the following:

3.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

3.2.2 Discontinued GH therapy for at least 1 month

AND

3.2.3 BOTH of the following:

3.2.3.1 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- GHRH and ARG
- ARG
- Glucagon

AND

3.2.3.2 ONE of the following peak GH values:

3.2.3.2.1 ITT less than or equal to 5 mcg/L

OR

3.2.3.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 mcg/L if BMI is less than 25 kg/m^2
- Less than or equal to 8 mcg/L if BMI is greater than or equal to 25 and less than 30 kg/m^2
- Less than or equal to 4 mcg/L if BMI is greater than or equal to 30 kg/m^2

OR

3.2.3.2.3 Glucagon less than or equal to 3 mcg/L

OR

3.2.3.2.4 ARG less than or equal to 0.4 mcg/L

AND

4 - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Omnitrope, Saizen, Saizenprep, Serostim, Zomacton, Zorbtive, Nutropin AQ Nuspin, Norditropin Flexpro, Sogroya, Ngenla, Skytrofa	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy [e.g., increase in total lean body mass, exercise capacity or IGF-1 (Insulin-like Growth Factor 1) and IGFBP-3 (Insulin-like growth factor binding protein 3) levels]

AND

2 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

3 - Prescribed by an endocrinologist

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV)-associated wasting syndrome or cachexia

AND

2 - Documentation of ONE of the following:

2.1 Unintentional weight loss of greater than 10 percent over the last 12 months

OR

2.2 Unintentional weight loss of greater than 7.5 percent over the last 6 months

OR

2.3 Loss of 5 percent body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) less than 20 kilograms per square meter (kg/m^2)

OR

2.5 ONE of the following:

2.5.1 ALL of the following:

- Patient is male
- BCM less than 35 percent of total body weight
- BMI less than 27 kg/m^2

OR

2.5.2 ALL of the following:

- Patient is female
- BCM less than 23 percent of total body weight

- BMI less than 27 kg/m^2

AND

3 - A nutritional evaluation has been completed since onset of wasting first occurred

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes)

AND

5 - Patient's anti-retroviral therapy has been optimized to decrease the viral load

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy [i.e., greater than or equal to 2 percent increase in body weight and/or body cell mass (BCM)]

AND

2 - ONE of the following targets or goals has not been achieved:

- Weight
- BCM

- Body Mass Index (BMI)

Product Name: Zorbtive*	
Diagnosis	Short Bowel Syndrome
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements)

AND

3 - Patient has not previously received 4 weeks of treatment with Zorbtive*

Notes	*Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied.

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency/Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Documentation of ALL of the following:

1.1.1 Diagnosis of severe primary Insulin-like Growth Factor 1 (IGF-1) deficiency

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone levels

AND

1.1.5 Documentation of open epiphyses on last bone radiograph

AND

1.1.6 The patient will not be treated with concurrent growth hormone therapy

AND

1.1.7 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

AND

1.2.2 Documentation of open epiphyses on last bone radiograph

AND

1.2.3 The patient will not be treated with concurrent growth hormone therapy

AND

1.2.4 Prescribed by an endocrinologist

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency/Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not obtained
- Expected adult height goal

AND **3** - Patient is not treated with concurrent growth hormone therapy **AND** **4** - Prescribed by an endocrinologist	
Notes	*Documentation of previous height, current height, and goal expected adult height will be required for renewal.

2 . Revision History

Date	Notes
12/6/2023	Removed Omnitrope and Zomacton from Non-preferred section. Upd ated T/F for Non-preferred section to add Omnitrope and Zomacton.

HCG

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-72481
Guideline Name	HCG
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	11/1/2020

1 . Criteria

Product Name: Novarel, Ovidrel, Brand Pregnyl, generic chorionic gonadotropin	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction	

Hemangeol

Prior Authorization Guideline

Guideline ID	GL-64375
Guideline Name	Hemangeol
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Hemangeol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of proliferating infantile hemangioma

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use generic propranolol oral solution

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Hemophilia Clotting Factors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123557
Guideline Name	Hemophilia Clotting Factors
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Corifact	
Diagnosis	Congenital Factor XIII Deficiency (i.e., Fibrin Stabilizing Factor Deficiency)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital factor XIII deficiency

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Tretten	
Diagnosis	Congenital Factor XIII Deficiency (i.e., Fibrin Stabilizing Factor Deficiency)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital factor XIII A-subunit deficiency

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Humate-P	
Diagnosis	Von Willebrand Disease (VWD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of severe von Willebrand disease

OR

1.2 BOTH of the following:

- Diagnosis of mild or moderate von Willebrand disease
- History of failure, contraindication or intolerance to treatment with desmopressin

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding

Product Name: Alphanate	
Diagnosis	Von Willebrand Disease (VWD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild or moderate von Willebrand disease

AND

2 - Used for peri-operative management of surgical bleeding

AND

3 - History of failure, contraindication or intolerance to treatment with desmopressin

Product Name: Wilate or Vonvendi	
Diagnosis	Von Willebrand Disease (VWD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of von Willebrand disease

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding
- Routine prophylactic treatment

Product Name: NovoSeven RT	
Diagnosis	Congenital Factor VII Deficiency
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital factor VII deficiency

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Routine prophylactic treatment of bleeding

Product Name: Advate, Alphanate, Humate-P, Hemofil M, KoAte, KoAte-DVI, Kogenate FS, Kovaltry, NovoEight, Nuwiq, Recombinate, Xyntha, or Xyntha Solofuse	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Eloctate	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician

AND

4 - ONE of the following:

4.1 BOTH of the following:

- Dose does not exceed 50 IU/kg
- Infusing no more frequently than every 4 days

OR

4.2 Requested dosage regimen does not exceed 12.5 IU/kg/day

OR

4.3 BOTH of the following:

4.3.1 Patient is less than 6 years of age

AND

4.3.2 ONE of the following:

- Pharmacokinetic (PK) testing results suggest that dosing more intensive than 50 IU/kg is required
- PK testing results suggest that dosing more frequently than every 3 to 5 days is required
- PK testing results suggest that dosing more intensive than 14.5 IU/kg/day is required

Product Name: Jivi

Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Peri-operative management of surgical bleeding
- Routine prophylactic treatment of bleeding
- Treatment of bleeding episodes

AND

3 - Patient has previously received Factor VIII replacement therapy

AND

4 - Patient is 12 years of age or older

AND

5 - Patient is not a candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician

AND

6 - Patient is not to receive routine infusions more than 2 times per week

Product Name: Afstyla	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate] as attested by the prescribing physician

AND

4 - ONE of the following:

4.1 Patient is not to receive routine infusions more frequently than 3 times per week

OR

4.2 BOTH of the following:

- Patient is less than 12 years of age
- Pharmacokinetic (PK) testing results suggest that more frequently than 3 times per week dosing is required

Product Name: Hemlibra	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of severe hemophilia A

AND

1.1.2 Documentation of endogenous factor VIII level less than 1% of normal factor VIII (< 0.01 IU/mL)

AND

1.1.3 Physician attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes

OR

1.2 All of the following:

1.2.1 One of the following:

1.2.1.1 BOTH of the following:

- Diagnosis of moderate hemophilia A
- Documentation of endogenous factor VIII level greater than or equal to 1% to less than 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

OR

1.2.1.2 Both of the following:

- Diagnosis of mild hemophilia A
- Documentation of endogenous factor VIII level greater than or equal to 5% (greater than 0.05 IU/mL)

AND

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

AND

1.2.3 Physician attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes

OR

1.3 BOTH of the following:

- Diagnosis of hemophilia A
- Patient has developed high-titer factor VIII inhibitors (greater than or equal to 5 Bethesda units [BU])

AND

2 - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name: FEIBA	
Diagnosis	Hemophilia A
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - One of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: NovoSeven RT, Obizur	
Diagnosis	Acquired factor VIII Hemophilia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired factor VIII hemophilia (e.g., acquired hemophilia A, Factor VIII deficiency)

AND

2 - Treatment or prevention of bleeding episodes

Product Name: Adynovate

Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - One of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician

AND

4 - One of the following:

4.1 BOTH of the following:

- Patient is not to receive routine infusions more frequently than 2 times per week
- Patient is not to receive a routine dose greater than 50 IU/kg

OR

4.2 ALL of the following:

- Patient is less than 12 years of age
- Patient is not to receive routine infusions more frequently than 2 times per week

- Patient is not to receive a routine dose greater than 70 IU/kg

Product Name: Esperoct	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - ONE of the following:

3.1 Patient is not to receive routine infusions more frequently than 2 times per week

OR

3.2 BOTH of the following:

- Patient is less than 12 years of age
- Pharmacokinetic (PK) testing results suggest that more frequent than 2 times per week dosing is required

Product Name: Wilate

Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

2.1 Routine prophylactic treatment of bleeding

OR

2.2 Treatment of bleeding episodes

Product Name: NovoSeven RT	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - One of the following:

- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: AlphaNine SD, Profilnine	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - One of the following:

- Routine prophylactic treatment
- Treatment of bleeding episodes

Product Name: BeneFIX, Rixubis, Alprolix, Idelvion, Ixinity, or Rebinyn	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - ONE of the following:

- Routine prophylactic treatment
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: FEIBA	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: NovoSeven RT	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - ONE of the following:

- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Fibryga, RiaSTAP	
Diagnosis	Fibrinogen Deficiency (i.e., Factor I deficiency)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia

AND

2 - Treatment of bleeding episodes

Product Name: NovoSeven RT	
Diagnosis	Glanzmann Thrombasthenia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Glanzmann's thrombasthenia

AND

2 - Refractory to platelet transfusions

AND

3 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding

Product Name: Coagadex	
Diagnosis	Congenital Factor X Deficiency
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital Factor X deficiency

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding
- Routine prophylactic treatment

2 . Background

Benefit/Coverage/Program Information

Background:

Advate, Xyntha, Xyntha Solofuse, Alphanate, Humate-P, Hemofil M, Koate, Koate-DVI, Kogenate FS, Kovaltry, NovoEight, Recombinate, Nuwiq, Eloctate, Jivi, Afstyla, Hemlibra, Adynovate, Esperoct, and FEIBA and are indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

- Control and prevention of bleeding episodes
- Peri-operative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Wilate is indicated in adolescents and adults with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes and on-demand treatment and control of bleeding episodes.

NovoSeven RT is indicated for the treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. It is also indicated in the treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia.

Corifact is indicated for routine prophylactic treatment and peri-operative management of surgical bleeding in adult and pediatric patients with congenital factor XIII deficiency.

Tretten is indicated for routine prophylaxis for bleeding with congenital factor XIII A-subunit deficiency.

Alphanate, Humate-P, Wilate, Vonvendi are indicated for von Willebrand disease for:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding
- Routine prophylactic treatment (Wilate and Vonvendi only)

Obizur is indicated for acquired factor VIII hemophilia (e.g., acquired hemophilia A, Factor VIII deficiency).

AlphaNine SD, Mononine, Profilnine/SD, BeneFIX, Rixubis, Ixinity, Alprolix, Idelvion, Rebinyn, FEIBA and NovoSeven RT are indicated for Hemophilia B.

Fibryga and RiaSTAP are indicated for congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Coagadex is indicated for congenital Factor X deficiency.

Table 1: Brand/generic designations of blood clotting products.

Product	Brand Name
Factor VIIa (recombinant)	NovoSeven® RT [coagulation factor VIIa (recombinant)] Sevenfact™ [coagulation factor VIIa (recombinant)-jncw]
Factor XIII (plasma-derived)	Corifact® [factor XIII concentrate (human)]
Factor VIII (plasma-derived)	Hemofil M® [antihemophilic factor (human)]
	Koate®-DVI [antihemophilic factor (human)]
Factor VIII (plasma-derived) / von Willebrand Factor Complex (plasma-derived)	Alphanate® [antihemophilic factor (human)]
	Humate-P® [antihemophilic factor (human)]
	Wilate® [antihemophilic factor (human)]
Factor VIII (recombinant)	Advate® [antihemophilic factor (recombinant)]

	Helixate® FS [antihemophilic factor (recombinant)]
	Kogenate® FS [antihemophilic factor (recombinant)]
	Kovaltry® [antihemophilic factor (recombinant)]
	Novoeight® [antihemophilic factor (recombinant)]
	Nuwiq® [antihemophilic factor (recombinant)]
	Recombinate® [antihemophilic factor (recombinant)]
	Xyntha® [antihemophilic factor (recombinant)]
	Xyntha® Solofuse™ [antihemophilic factor (recombinant)]
Factor IX (plasma-derived)	AlphaNine® SD [coagulation factor IX (human)]
	Mononine® [coagulation factor IX (human)]
	Profilnine SD® [factor IX complex human)]
Factor IX (recombinant)	BeneFIX® [coagulation factor IX (recombinant)]
	Ixinity® [coagulation factor IX (recombinant)]
	Rixubis® [coagulation factor IX (recombinant)]
Factor IX (recombinant), long-acting	Alprolix® [coagulation factor IX (recombinant), Fc fusion protein]
	Idelvion® [coagulation factor IX (recombinant), albumin fusion protein]
	Rebinyn® [coagulation factor IX (recombinant), GlycoPEGylated]
Anti-Inhibitor Coagulant Complex (plasma-derived)	FEIBA® [anti-inhibitor coagulant complex (human)]
Fibrinogen Concentrate (plasma-derived)	RiaSTAP® [fibrinogen concentrate (human)]
	Fibryga® [fibrinogen (human)]
Factor XIII A-subunit (recombinant)	Tretten® [coagulation factor XIII A-subunit (recombinant)]
Factor VIII (recombinant), long-acting	Adynovate® [antihemophilic factor (recombinant), PEGylated]
	Afstyla® [antihemophilic factor (recombinant)]
	Eloctate® [antihemophilic factor (recombinant), Fc fusion protein]
	Esperoct® [antihemophilic factor (recombinant), glycopegylated-exei]
	Jivi® [antihemophilic factor (recombinant), PEGylated-aucl]
Factor VIII (recombinant), porcine sequence	Obizur® [antihemophilic factor (recombinant), porcine sequence]

Factor X (plasma-derived)	Coagadex® [coagulation factor X (human)]
Von Willebrand Factor (recombinant)	Vonvendi® [von Willebrand factor (recombinant)]
Bispecific factor IXa- and factor X-directed antibody	Hemlibra® (emicizumab-kxwh)

3 . Revision History

Date	Notes
3/21/2023	Renamed GL and updated to match FFS

Hepatitis C

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126365
Guideline Name	Hepatitis C
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Brand Sofosbuvir-velpatasvir*, Mavyret*	
Diagnosis	Hepatitis C Retreatment
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic Hepatitis C infection status which has been confirmed by detectable serum hepatitis C virus (HCV) RNA (ribonucleic acid) by quantitative assay completed within the past 90 days from the date of the prior authorization request

AND

2 - Age of the patient is Food and Drug Administration (FDA) approved for the specific HCV DAA (Direct Acting Antiviral) product

AND

3 - The prescribing provider assesses the patient's ability to adhere to the HCV DAA treatment plan and attests the assessment has been documented within the clinical record. For patients that would benefit from adherence aids, the treating provider shall refer the patient to a treatment adherence program

AND

4 - Patient agrees to adhere to the proposed course of treatment, including taking medications as prescribed, attending follow-up appointments, and, if applicable, participating in a treatment adherence program

AND

5 - ONE of the following:

5.1 Patient has been screened for Hepatitis A and B and has received one Hepatitis A and one Hepatitis B vaccine prior to requesting treatment

OR

5.2 Patient demonstrates laboratory evidence of immunity to Hepatitis A and B

AND

6 - The Prescriber must submit the following information with the request for HCV DAA medications to be considered:

6.1 HCV treatment history and responses to treatment

AND

6.2 Current medication list

AND

6.3 Laboratory results for ALL of the following:

- HCV screen test results
- Genotype and current baseline HCV viral load
- Total bilirubin
- Albumin level
- International Normalized Ratio (INR)
- Creatinine Clearance (CrCl) or Glomerular Filtration Rate (GFR)
- Liver Function Tests (LFTs)
- Complete Blood Count (CBC)
- Viral resistance status (when applicable)
- Hepatic status (Child Pugh Score)

AND

7 - If the HCV DAA product is being used in combination with ribavirin, the prescribing provider attests to monitoring hemoglobin levels periodically

AND

8 - The prescribing provider attests to monitoring HCV RNA levels obtained at 12- and 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR)

AND

9 - DAA HCV treatment coverage is NOT provided for ANY of the following:

9.1 DAA dosages greater than the FDA approved maximum dosage

OR

9.2 Patients whose comorbidities are such that their life expectancy is one year or less

OR

9.3 Patients currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.)

OR

9.4 Lost or stolen medication absent of good cause

OR

9.5 Fraud, waste, or misuse of HCV DAA medications

Notes	Approval length: Mavyret = 8 Week(s), Brand Sofosbuvir-velpatasvir = 12 Weeks(s). *Preferred drugs Mavyret and Brand Sofosbuvir-velpatasvir will be approved without requiring prior authorization ONE time per lifetime. Requests for retreatment or non-preferred drugs will require PA. Refer to AASLD for specific approval durations AASLD: https://www.hcvguidelines.org/contents

Product Name: Brand Epclusa, Brand Harvoni, Brand Ledipasvir-sofosbuvir, Sovaldi, Zepatier	
Diagnosis	Hepatitis C
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient was adherent to previous DAA therapy as evidenced by submission of medical records and/or pharmacy prescription claims

OR

1.2 If prior therapy was discontinued due to adverse effects from the DAA, the medical

record shall be provided which documents these adverse effects and recommendation of discontinuation by treatment provider

AND

2 - The patient's ability to adhere to the planned course of retreatment has been assessed by the treating provider and documented within the clinical record

AND

3 - Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when BOTH of the following are true:

- Required for regimens whereby the FDA (Food and Drug Administration) requires such testing prior to treatment to ensure clinical appropriateness
- Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen

AND

4 - HCV retreatment with a DAA shall NOT be approved for ANY of the following:

4.1 The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy

OR

4.2 Is considered an experimental service

OR

4.3 Monotherapy of Sofosbuvir (Sovaldi)

OR

4.4 DAA dosages greater than the FDA approved maximum dosage

OR

4.5 Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request

OR

4.6 Patients whose comorbidities are such that their life expectancy is one year or less

OR

4.7 Patients currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.)

OR

4.8 Lost or stolen medication absent of good cause

OR

4.9 Fraudulent use of HCV DAA medications

AND

5 - If the request is for brand Epclusa or brand Harvoni, BOTH of the following:

5.1 The patient has a therapeutic failure, contraindication, or intolerance to the generic as evidenced by submission of medical records or claims history

AND

5.2 The prescriber must submit the FDA MedWatch form

Notes	*The approval length should be as recommended per AASLD. Refer t o AASLD for specific approval durations. AASLD: https://www.hcvguid elines.org/contents

Product Name: Brand Harvoni, Brand Ledipasvir-sofosbuvir	
Diagnosis	Hepatitis C Retreatment
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - ONE of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 BOTH of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

Product Name: Vosevi, Viekira Pak	
Diagnosis	Hepatitis C
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - ONE of the following:

2.1 Patient is a previous relapser to an NS5A-based regimen [e.g., Daklinza (daclatasvir); Epclusa (sofosbuvir/velpatasvir); Harvoni (ledipasvir/sofosbuvir); Mavyret (glecaprevir/pibrentasvir); Technivie (ombitasvir/paritaprevir/ritonavir); Viekira (ombitasvir/paritaprevir/ritonavir & dasabuvir); Zepatier (elbasvir/grazoprevir)]

OR

2.2 Patient is a previous relapser to a sofosbuvir-based regimen without an NS5A inhibitor

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Vosevi, Viekira Pak	
Diagnosis	Hepatitis C: Prior Failure to Vosevi/Viekira Pak
Approval Length	24 Week(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - BOTH of the following:

2.1 Patient had a prior treatment failure with Vosevi or Viekira

AND

2.2 Used in combination with ribavirin

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Pegasys	
Diagnosis	Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

3 - Will be used as part of a combination antiviral treatment regimen

Product Name: Ribavirin tablets and capsules	
Diagnosis	Hepatitis C
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Used in combination with a direct-acting agent

2 . Revision History

Date	Notes
6/6/2023	Specified Retreatment in first criteria section diagnosis, cleaned up n ote, spelled out acronym for RNA.

Hereditary Angioedema (HAE) Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126372
Guideline Name	Hereditary Angioedema (HAE) Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Cinryze, Haegarda, Orladeyo, Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of hereditary angioedema (HAE) confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal

- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of a FXII (factor XII), angiopoietin-1, or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - For prophylaxis against HAE attacks

AND

3 - ONE of the following:

- If the request is for Takhzyro, patient is 2 years of age or older
- If the request is for Cinryze or Haegarda, patient is 6 years of age or older
- If the request is for Orladeyo, patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with ONE of the following:

- Immunologist
- Allergist

AND

5 - If the request is non-preferred*, ONE of the following:

5.1 Submission of medical records documenting a history of failure, contraindication, or intolerance to a preferred* HAE agent

OR

5.2 Submission of medical records documenting that the patient is currently on the requested therapy

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Cinryze (off-label), Berinert, Brand Firazyr, generic icatibant acetate, Kalbitor, Ruconest, Sajazir	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of hereditary angioedema (HAE) confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of a FXII, angiopoietin-1, or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - For the treatment of acute HAE attacks

AND

3 - Not used in combination with other approved treatments for acute HAE attacks

AND

4 - ONE of the following:

- If the request is for Cinryze, patient is 6 years of age or older
- If the request is for Kalbitor, patient is 12 years of age or older
- If the request is for Firazyr, icatibant, or Sajazir, patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with ONE of the following:

- Immunologist
- Allergist

AND

6 - If the request is for generic icatibant, submission of medical records documenting a history of failure or intolerance to Brand Firazyr

AND

7 - If the request is for Sajazir or Ruconest, ONE of the following:

7.1 Submission of medical records documenting a history of failure, contraindication, or intolerance to a preferred* HAE agent

OR

7.2 Submission of medical records documenting that the patient is currently on the requested therapy

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
6/6/2023	Updated GPI for Firazyr, icatibant, and Sajazir, updated T/F criteria for Brand Firazyr.

Hetlioz, Hetlioz LQ (tasimelteon)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117677
Guideline Name	Hetlioz, Hetlioz LQ (tasimelteon)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) confirmed by meeting ONE of the following conditions:

1.1 Assessment of at least one physiologic circadian phase marker [e.g., measurement of

urinary melatonin levels, dim light melatonin onset (as measured in blood or saliva), assessment of core body temperature]

OR

1.2 If assessment of at least one physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient is totally blind (has no light perception)*

AND

3 - Patient is 18 years of age or older

AND

4 - Patient has received at least 3 months of continuous therapy (i.e., 3 consecutive months of daily treatment) under the guidance of a physician who specializes in the treatment of sleep disorders of BOTH of the following:

- Melatonin
- Rozerem (ramelteon)

AND

5 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Notes	*Requests for patients who are sighted (non-blinded) will be reviewed on a case-by-case basis

Product Name: Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep)

AND

2 - Submission of patient's sleep log demonstrating positive clinical response to therapy

Product Name: Hetlioz capsule	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Submission of test results confirming patient has microdeletion of the chromosome band 17p11.2 by fluorescent in situ hybridization (FISH) analysis

AND

3 - Patient is 16 years of age or older

AND

4 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

5 - Patient has received at least 3 months of continuous therapy (i.e., 3 consecutive months of daily treatment) under the guidance of a physician who specializes in the treatment of sleep disorders of BOTH of the following

- Melatonin
- Rozerem (ramelteon) (unless contraindicated due to patient age)

AND

6 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Submission of test results confirming patient has microdeletion of the chromosome band 17p11.2 by fluorescent in situ hybridization (FISH) analysis

AND

3 - Patient is 3 through 15 years of age

AND

4 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

5 - Patient has received at least 3 months of continuous therapy (i.e., 3 consecutive months of daily treatment) of melatonin under the guidance of a physician who specializes in the treatment of sleep disorders

AND

6 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule, Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

AND

2 - Submission of patient's sleep log demonstrating positive clinical response to therapy

2 . Revision History

Date	Notes
12/5/2022	Added note. Matched AZ FFS guideline

HIV (Fuzeon, Selzentry)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115887
Guideline Name	HIV (Fuzeon, Selzentry)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Brand Selzentry tablets, generic maraviroc tablets, Selzentry oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

1.1.3 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

AND

2 - For generic maraviroc tablets and Selzentry oral solution ONLY; history of failure or intolerance to Brand Selzentry tablets

Product Name: Fuzeon	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has been diagnosed with multidrug-resistant HIV-1 infection

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

1.1.3 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

2 . Revision History

Date	Notes
10/24/2022	New GL

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137438
Guideline Name	Humira (adalimumab) and adalimumab biosimilars
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Humira	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of

failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Humira	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Humira	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Adult Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

OR

2.2 Patient has lost response or intolerant to infliximab (e.g., Remicade, Inflectra, Renflexis)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Pediatric Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Adult Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Humira	
Diagnosis	Hidradenitis Suppurativa
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Hidradenitis Suppurativa
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Humira	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as ONE of the following:

- intermediate
- posterior
- panuveitis

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE corticosteroid (e.g., prednisolone, prednisone) at maximally indicated dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at a maximally indicated dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

5 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

6 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

Product Name: Non-Preferred: Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Brand Adalimumab-fkjp, Hyrimoz, Brand Adalimumab-adaz, Idacio, Yuflyma, Yusimry	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried and failed Humira

2 . Revision History

Date	Notes
12/6/2023	Added Abrilada. Updated Humira, Amjevita and Yuflyma GPIs.

Hydroxychloroquine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64785
Guideline Name	Hydroxychloroquine
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Plaquenil, generic hydroxychloroquine	
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 Treatment of chronic discoid lupus erythematosus or systemic lupus erythematosus

OR

1.2 Treatment of rheumatoid arthritis

OR **1.3** Prophylaxis of malaria in geographic areas where chloroquine resistance is not reported **OR** **1.4** Treatment of uncomplicated malaria	
Notes	Authorization will be issued for 6 months up to a quantity of 120 tablets per 30 days.

2 . Revision History

Date	Notes
4/6/2020	C&S Implementation

Hyftor (sirolimus) topical gel

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115888
Guideline Name	Hyftor (sirolimus) topical gel
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Hyftor	
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of facial angiofibroma associated with tuberous sclerosis complex

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is not a candidate for laser therapy or surgical treatments

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Hyftor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in size or redness of facial angiofibroma)

2 . Revision History

Date	Notes
10/21/2022	new GL

Igalmi (dexmedetomidine)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115889
Guideline Name	Igalmi (dexmedetomidine)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Igalmi	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Schizophrenia
- Bipolar I or II disorder

AND

2 - For the treatment of acute agitation

AND

3 - Trial and failure, contraindication or intolerance to at least two preferred products used in acute agitation (e.g., olanzapine, ziprasidone)

AND

4 - Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid)

2 . Revision History

Date	Notes
10/24/2022	New

Ilaris (canakinumab)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136016
Guideline Name	Ilaris (canakinumab)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndromes [Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency(MKD), Familial Mediterranean Fever(FMF)]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) confirming a diagnosis of one of the following periodic fever syndromes:	

- Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
- Tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS)
- Hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS/mevalonate kinase deficiency (MKD)
- Familial Mediterranean Fever (FMF)

AND

2 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Immunologist

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Patients diagnosed with Familial Mediterranean Fever (FMF) have a history of failure, contraindication, or intolerance to colchicine (applies to diagnosis of FMF ONLY)

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndrome [CAPS, TRAPS, HIDS/MKD, FMF]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy [defined as a decrease in frequency or severity of attacks, or a decrease in index disease flare or normalization of CRP (C-reactive protein)]

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of active systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Immunologist

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroids (e.g., prednisone)
- Methotrexate
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Immunologist

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Gout Flares
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of gout flares

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ALL of the following:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)
- Colchicine
- Corticosteroids (e.g., prednisone)

AND

3 - Patient has not received Ilaris in the last 12 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Nephrologist

2 . Revision History

Date	Notes
11/6/2023	Update GL name to Ilaris (canakinumab)

Ilumya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110679
Guideline Name	Ilumya
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Ilumya	
Diagnosis	Chronic Moderate to Severe Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure, to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Ilumya therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Ilumya	
Diagnosis	Chronic Moderate to Severe Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ilumya therapy

AND

2 - Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Immune Globulin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110735
Guideline Name	Immune Globulin
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Asthma (severe, persistent, high-dose steroid-dependent)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Severe asthma

- Persistent asthma
- High-dose steroid-dependent asthma

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient is receiving optimal conventional asthma therapy (e.g., high-dose inhaled glucocorticoids, short- and long-acting inhaled β agonists)

AND

4 - History of failure, contraindication, or intolerance to at least TWO of the following:

- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

5 - Patient has required continuous oral glucocorticoid therapy for a minimum of 2 months prior to the decision to initiate immune globulin therapy

AND

6 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

7 - Prescribed by or in consultation with a pulmonologist or allergist or immunologist

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Asthma (severe, persistent, high-dose steroid-dependent)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Extensive and debilitating disease

AND

4 - History of failure, contraindication, or intolerance to systemic corticosteroids with

concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil)

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 to 2,000 milligrams (mg) per kilogram (kg) per month divided into 3 equal doses, each given over 3 consecutive days or 400 mg per kg per day given over 5 consecutive days per month. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

6 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Bone Marrow Transplant (BMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following uses:

- Prevention of acute graft vs. host disease (GVHD)
- Prevention of infection

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Confirmed allogeneic bone marrow transplant within the last 100 days

AND

4 - Documented severe hypogammaglobulinemia [Immunoglobulin (IgG) less than 400 milligrams (mg) per deciliter (dL)]

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 500 mg per kilogram (kg) once weekly for the first 90 days of therapy, then monthly up to 360 days after transplantation

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify

Diagnosis	Bone Marrow Transplant (BMT)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: : HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy as confirmed by ALL of the following:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb

AND

1.3 Electrodiagnostic findings [consistent with European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) guidelines for definite chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)] indicating at least ONE of the following criteria are present:

- Motor distal latency prolongation in 2 nerves
- Reduction of motor conduction velocity in 2 nerves
- Prolongation of F-wave latency in 2 nerves
- Absence of F-waves in at least 1 nerve
- Partial motor conduction block of at least 1 motor nerve
- Abnormal temporal dispersion in at least 2 nerves
- Distal compound muscle action potential (CMAP) duration increase in at least 1 nerve

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

AND

2 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in B-cell Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - ONE of the following:

- Documented hypogammaglobulinemia [Immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]

- History of bacterial infection(s) associated with B-cell CLL

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 milligrams (mg) per kilogram (kg) every 3 to 4 weeks

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in B-cell Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Dermatomyositis or polymyositis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dermatomyositis or polymyositis

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate)

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days administered as monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

5 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Dermatomyositis or polymyositis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is newly diagnosed with insulin dependent (type 1) diabetes mellitus

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient is not a candidate for or is refractory to insulin therapy

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.(Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Feto-neonatal Alloimmune Thrombocytopenia (AIT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For pregnant women all of the following:

1.1 Diagnosis of feto-neonatal alloimmune thrombocytopenia (AIT)

AND

1.2 ONE of the following:

- Previously affected pregnancy
- Family history of the disease
- Platelet alloantibodies found on screening

AND

1.3 ONE of the following:

1.3.1 Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) once weekly until delivery

OR

1.3.2 BOTH of the following:

- Fetus or newborn is considered to be at high risk for developing intracranial hemorrhage or other severe complication of AIT
- IVIG dose does not exceed 2,000 mg/kg once weekly until delivery

AND

2 - For newborns all of the following:

2.1 Diagnosis of feto-neonatal alloimmune thrombocytopenia

AND

2.2 Thrombocytopenia that persists after transfusion of antigen-negative compatible platelets

AND

3 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Feto-neonatal Alloimmune Thrombocytopenia (AIT)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Graves' ophthalmopathy Guillain-Barré syndrome (GBS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Guillain-Barré Syndrome

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Severe disease requiring aid to walk

AND

4 - Onset of neuropathic symptoms within the last four weeks

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Graves' ophthalmopathy Guillain-Barré syndrome (GBS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of bacterial infection in pediatric HIV
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV disease

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient age less than or equal to 13 years of age

AND

4 - ONE of the following:

- Documented hypogammaglobulinemia [Immunoglobulin (IgG) less than 400 milligrams (mg) per deciliter (dL)]
- Functional antibody deficiency as demonstrated by either poor specific antibody titers or recurrent bacterial infections

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 28 days

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of bacterial infection in pediatric HIV
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify

Diagnosis	Immune thrombocytopenia [Idiopathic thrombocytopenic purpura (ITP)]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

- Diagnosis of acute thrombocytopenic purpura (ITP)
- Documented platelet count less than 50 x 10^9 per Liter (L) (obtained within the past 30 days)
- Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram(kg) per day for 1 to 2 days

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic thrombocytopenic purpura (ITP)

AND

1.2.2 History of failure, contraindication, or intolerance to at least ONE of the following:

- Corticosteroids
- Splenectomy

AND

1.2.3 IVIG dose does not exceed 2,000 mg per kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - If the request is for a non-preferred product, there is a history of failure, contraindication or intolerance to 3 preferred products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to all of the preferred products

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Immune thrombocytopenia [Idiopathic thrombocytopenic purpura (ITP)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Kawasaki Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Kawasaki disease

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable

- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 4,000 milligrams (mg) per kilograms (kg) for five consecutive days or a single dose of 2,000 mg per kg

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Kawasaki Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids)

AND

4 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous Immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify

Diagnosis	Lambert-Eaton Myasthenic Syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lennox Gastaut Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication or intolerance to initial treatment with traditional anti-epileptic pharmacotherapy (e.g., lamotrigine, phenytoin, valproic acid)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 milligrams (mg) per kilogram (kg) per day given for 4 to 5 consecutive days. IVIG administration may be repeated monthly as needed in patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

5 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lennox Gastaut Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Multifocal Motor Neuropathy (MMN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy as confirmed by ALL of the following:

- Weakness with slowly progressive or stepwise progressive course over at least one month

- Asymmetric involvement of two or more nerves
- Absence of motor neuron signs and bulbar signs

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,400 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Multifocal Motor Neuropathy (MMN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,400 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

4 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - ONE of the following:

- Documented hypogammaglobulinemia [immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]
- History of bacterial infection(s) associated with multiple myeloma

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 3 to 4 weeks

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C

- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Relapsing Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary- progressive MS with relapses, progressive-relapsing MS with relapses)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy

AND

4 - History of failure, contraindication, or intolerance to at least TWO of the following agents:

- Aubagio (teriflunomide)
- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Copaxone/Glatopa (glatiramer acetate)
- Extavia (interferon beta-1b)
- Gilenya (fingolimod)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Mayzent (siponimod)
- Ocrevus (ocrelizumab)
- Plegridy (peginterferon beta-1a)
- Rebif (interferon beta-1a)
- Tecfidera (dimethyl fumarate)
- Tysabri (natalizumab)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Induction, when indicated, does not exceed a dose of 400 milligrams (mg) per kilogram (kg) daily for up to five days

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Relapsing Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Medical records, including findings of interval examination including neurological deficits incurred and assessment of disability [e.g., Expanded Disability Status Scale (EDSS), Functional Systems Score (FSS), Multiple Sclerosis Functional Composite (MSFC), Disease Steps (DS)]

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS)

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy

AND

4 - Diagnosis continues to be the relapsing forms of multiple sclerosis (MS)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligram (mg) per kilogram (kg) monthly

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Myasthenia Gravis - Exacerbation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Evidence of myasthenia exacerbation, defined by at least ONE of the following symptoms in the last month

- Difficulty swallowing
- Acute respiratory failure
- Major functional disability responsible for the discontinuation of physical activity
- Recent immunotherapy treatment with a checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab)]

AND

4 - ONE of the following:

- History of failure, contraindication, or intolerance to immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis
- Currently receiving immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Refractory Myasthenia Gravis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory generalized myasthenia gravis by or in consultation with a physician or center with expertise in management of myasthenia gravis

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documentation that the disease status is unchanged or worsening (persistent or worsening symptoms that limit functioning) despite failure, contraindication, or intolerance to BOTH of the following (used in adequate doses and duration):

- Corticosteroids
- Two immunomodulator therapies (e.g., azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus)

AND

4 - Currently receiving immunomodulator therapy (e.g., corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus), used in adequate doses, for long-term management of myasthenia gravis

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Myasthenia Gravis –Exacerbation and Refractory Myasthenia Gravis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Neuromyelitis Optica
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by a neurologist confirming ALL of the following:

1.1 Serologic testing for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) or Neuromyelitis optica immunoglobulin G (NMO-IgG) antibodies has been performed

AND

1.2 ONE of the following:

1.2.1 If AQP4-IgG/NMO-IgG positive, past medical history of ONE of the following:

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

OR

1.2.2 If AQP4-IgG/NMO-IgG negative, past medical history of TWO of the following:

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome

- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

AND

1.3 Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to at least TWO of the following:

- Azathioprine
- Corticosteroids
- Mycophenolate mofetil
- Rituximab
- Soliris (eculizumab)

AND

4 - Patient is not receiving immune globulin in combination with either of the following:

- Rituximab
- Soliris (eculizumab)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligram (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Neuromyelitis Optica
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with immune globulin

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by BOTH of the following:

2.1 Reduction in the number and or severity of relapses or signs and symptoms of neuromyelitis optica spectrum disorder (NMOSD)

AND

2.2 Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting immune globulin. (NOTE: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on immune globulin therapy will be considered as treatment failure.)

AND

3 - Patient is not receiving immune globulin in combination with either of the following:

- Rituximab
- Soliris (eculizumab)

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Posttransfusion Purpura
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of posttransfusion purpura

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) for 2 days

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Posttransfusion Purpura

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Post B-Cell Targeted Therapies
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation confirming previous treatment of B-cell targeted therapy within the last 100 days [e.g., CAR-T (e.g., Kymriah), Rituxan (rituximab), Besponsa (inotuzumab ozogamicin)]

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - BOTH of the following:

- Documented hypogammaglobulinemia [immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]
- History of bacterial infection(s) associated with B-cell depletion

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 4 weeks, up to 360 days after discontinuation of B-cell depleting therapy

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Post B-Cell Targeted Therapies
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Primary Immunodeficiency Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunodeficiency

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable

- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by ONE of the following:

- Documented failure to produce antibodies to specific antigens
- History of significant recurrent infections

AND

4 - Initial intravenous immunoglobulin (IVIG) dose is 200 to 800 milligrams (mg) per kilogram (kg) every 3 to 4 weeks, based on product prescribing information, and titrated based upon patient response (For subcutaneous immune globulin (SCIG) products, FDA-labeled dosing and conversion guidelines will used to determine benefit coverage.)

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Primary Immunodeficiency Syndromes
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Rasmussen Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of ONE of the following demonstrating that:

- Short term amelioration of encephalitis is needed prior to definitive surgical therapy
- Disease symptoms (e.g., seizures) persist despite surgical treatment
- The patient is not a candidate for surgical treatment

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Rasmussen Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Stiff-Person Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stiff-person syndrome

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication or intolerance to GABAergic (gamma-aminobutyric acid analogs) medication (e.g., baclofen, benzodiazepines)

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Stiff-Person Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical improvement from baseline

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

4 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Thrombocytopenia, secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of thrombocytopenia secondary to Hepatitis C Virus (HCV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.2 Both of the following:

- Diagnosis of thrombocytopenia secondary Human Immunodeficiency Virus (HIV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.3 Diagnosis of thrombocytopenia secondary to pregnancy

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documented platelet count less than 50 x 10^9 per liter (L) (obtained within the past 30 days)

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) per day for 1 to 2 days

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Thrombocytopenia, secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of thrombocytopenia secondary to Hepatitis C Virus (HCV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.2 Both of the following:

- Diagnosis of thrombocytopenia secondary Human Immunodeficiency Virus (HIV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.3 Diagnosis of thrombocytopenia secondary to pregnancy

AND

2 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	All other indications
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Autoimmune Uveitis
- Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants
- Enteroviral Meningoencephalitis
- IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Lymphoproliferative disease (treatment of bacterial infections)
- Monoclonal gammopathy
- Paraproteinemic neuropathy
- Renal transplantation (prevention or treatment of acute humoral rejection)
- Severe Rheumatoid arthritis
- Rotaviral enterocolitis
- Staphylococcal toxic shock
- Toxic epidermal necrolysis or Stevens-Johnson syndrome
- Urticaria (delayed pressure)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	All other indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND **3** - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Impavido

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124423
Guideline Name	Impavido
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Impavido	
Approval Length	28 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of ONE of the following:

- Visceral leishmaniasis due to Leishmania donovani
- Cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, or Leishmania panamensis
- Mucosal leishmaniasis due to Leishmania braziliensis
- Primary Amebic Meningoencephalitis (PAM)
- Keratitis due to Acanthamoeba

- Amebic encephalitis due to Balamuthia mandrillaris

Inbrija

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-80270
Guideline Name	Inbrija
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/1/2021

1 . Criteria

Product Name: Inbrija	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson’s disease

AND

2 - Inbrija will be used as intermittent treatment for OFF episodes

AND

3 - Prescribed by, or in consultation with, a neurologist or specialist in the treatment of Parkinson's disease

AND

4 - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

5 - Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

6 - History of failure, contraindication, or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

Product Name: Inbrija	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inbrija therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
1/27/2021	Updated criteria for initial authorization. Copied from 79944

Infliximab Products

Prior Authorization Guideline

Guideline ID	GL-136018
Guideline Name	Infliximab Products
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Avsola, Inflectra	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active RA (rheumatoid arthritis)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer)

Product Name: Avsola, Inflectra	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Avsola, Inflectra	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of active PsA (psoriatic arthritis)

AND

2 - ONE of the following:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer)

Product Name: Avsola, Inflectra	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Avsola, Inflectra	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - ONE of the following:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer)

Product Name: Avsola, Inflectra	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy as evidenced by ONE of the following:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Avsola, Inflectra	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to TWO different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer)

Product Name: Avsola, Inflectra	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least ONE of the following:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Avsola, Inflectra	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of ONE of the following:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - ONE of the following:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values [e.g., C-reactive protein (CRP)]
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer)

Product Name: Avsola, Inflectra	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least ONE of the following:

- Improvement in intestinal inflammation [e.g., mucosal healing, improvement of lab values (platelet counts, erythrocyte sedimentation rate, C-reactive protein level)] from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values [e.g., hemoglobin, ESR (erythrocyte sedimentation rate), CRP (C-reactive protein)]
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer)

Product Name: Avsola, Inflectra	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least ONE of the following:

- Improvement in intestinal inflammation [e.g., mucosal healing, improvement of lab values (platelet counts, erythrocyte sedimentation rate, C-reactive protein level)] from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra	
Diagnosis	Sarcoidosis [Off-label]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with ONE of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE corticosteroid (e.g., prednisone)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer)

Product Name: Avsola, Inflectra	
Diagnosis	Sarcoidosis [Off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy

2 . Revision History

Date	Notes
11/6/2023	Updated Infliximab naming convention. No changes to clinical criteria .

Ingrezza (valbenazine)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136013
Guideline Name	Ingrezza (valbenazine)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Ingrezza	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia (TD) secondary to a centrally acting dopamine receptor blocking agent (DRBA)

AND

2 - Prescribed by or in consultation with a psychiatrist or neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Patient has an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of the AIMS items 1 through 9

AND

5 - Ingrezza is not prescribed concurrently with Austedo or tetrabenazine

AND

6 - - Dose does not exceed 80 mg per day

Product Name: Ingrezza	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline AIMS score in any one of the AIMS items 1 through 9

AND

2 - Ingrezza is not prescribed concurrently with Austedo or tetrabenazine

AND

3 - Dose does not exceed 80 mg per day

Product Name: Ingrezza	
Diagnosis	Chorea Associated with Huntington's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Dose does not exceed 80 mg per day

Product Name: Ingrezza

Diagnosis	Chorea Associated with Huntington’s Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Dose does not exceed 80 mg per day

2 . Revision History

Date	Notes
11/7/2023	Updated guideline name. Added new criteria for new indication of ch orea associated with Huntington's Disease. Removed verbiage of "1 capsule" in max dose criterion as other strengths are available.

Inhaled Corticosteroids

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121158
Guideline Name	Inhaled Corticosteroids
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Alvesco, Arnuity Ellipta, Asmanex HFA, Qvar Redihaler	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - History of failure, contraindication, intolerance to a majority (not more than 3) of the following preferred inhaled corticosteroids:

- Asmanex Twisthaler (mometasone)
- Flovent Diskus (fluticasone)
- Flovent HFA (fluticasone)
- Pulmicort Flexhaler (budesonide)
- budesonide respule (generic)

2 . Revision History

Date	Notes
2/9/2023	Removed therapeutic duplication criteria section.

Injectable Oncology Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132894
Guideline Name	Injectable Oncology Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Synribo, Elrexfio, Talvey	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
9/11/2023	Added Elrexfio and Talvey

Inqovi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123559
Guideline Name	Inqovi
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Inqovi	
Diagnosis	Myelodysplastic Syndrome (MDS), Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of myelodysplastic syndrome (MDS)

AND

1.2 Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

OR

2 - Diagnosis of chronic myelomonocytic leukemia (CMML)

Product Name: Inqovi	
Diagnosis	Myelodysplastic Syndrome (MDS), Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inqovi therapy

Product Name: Inqovi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Inqovi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inqovi therapy

Insulin Pen Needles and Syringes

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135050
Guideline Name	Insulin Pen Needles and Syringes
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Non-preferred insulin pen needles and insulin syringes	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is non-preferred*, history of failure to a preferred* BD (Becton Dickinson) insulin pen needle or syringe as confirmed by claims history or submission of medical records

OR

2 - If the request is non-preferred*, physician has provided documentation as to why the patient is unable to use a preferred* BD product (document rationale)	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: All insulin pen needles and insulin syringes	
Diagnosis	Requests exceeding 6 pen needles or syringes per day*
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Physician confirmation that the patient requires a greater quantity because of more frequent delivery of insulin	
Notes	*The quantity limit for both pen needles and syringes is 6 of each per day.

2 . Revision History

Date	Notes
10/16/2023	Added updated GPIs to GPI Tables.

Insulins, Concentrated

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-112396
Guideline Name	Insulins, Concentrated
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Humulin R U-500 kwikpen and vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, intolerance, or contraindication to ALL of the following:

- Novolog or Humalog
- Lantus
- Levemir

OR **2** - There is a reason or special circumstance the patient needs to use a concentrated insulin product

2 . Revision History

Date	Notes
8/26/2022	C&S to match FFS 10.1.22

Iron Chelators

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110588
Guideline Name	Iron Chelators
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox

Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of transfusional iron overload due to thalassemia syndromes

AND

1.2 Current chelation therapy is inadequate [e.g., Desferal (deferoxamine), Exjade (deferasirox)]

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome

AND

1.2 Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with Exjade or Jadenu

AND

1.3 Patient has serum ferritin levels consistently greater than 300 micrograms per liter prior to initiation of treatment with Exjade or Jadenu

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Irritable Bowel Syndrome-Diarrhea

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110311
Guideline Name	Irritable Bowel Syndrome-Diarrhea
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Lotronex, generic alosetron	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

AND

2 - Symptoms for at least 6 months

AND

3 - Patient was female at birth

AND

4 - Age greater than or equal to 18 years

AND

5 - History of failure, contraindication, or intolerance to TWO of the following:

- Antispasmodic agent (e.g. dicyclomine)
- Antidiarrheal agents (e.g. loperamide)
- Tricyclic antidepressant (e.g. amitriptyline)

Product Name: Brand Lotronex, generic alosetron	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lotronex therapy

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

AND

2 - History of failure, contraindication, or intolerance to TWO of the following:

- Antispasmodic agent (e.g. dicyclomine)
- Antidiarrheal agents (e.g. loperamide)
- Tricyclic antidepressant (e.g. amitriptyline)

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Viberzi therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Isotretinoin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126375
Guideline Name	Isotretinoin
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Brand Absorica, Absorica LD, Amnesteem, Claravis, generic isotretinoin caps, Myorisan, Zenatane, Accutane	
Diagnosis	Oncology Uses (Off Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for an oncology indication meeting National Comprehensive Cancer Network (NCCN) with a Category of Evidence and Consensus of 1, 2A, or 2B

OR

2 - Used for an oncology indication from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology

Product Name: Brand Absorica, Absorica LD, Amnesteem, Claravis, generic isotretinoin caps, Myorisan, Zenatane, Accutane	
Approval Length	5 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy

OR

1.2 Diagnosis of treatment resistant acne

AND

2 - History of failure, contraindication, or intolerance to an adequate trial on TWO of the following conventional therapy regimens:

- Topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin)]
- Oral antibiotic [e.g., Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
- Topical antibiotic with or without benzoyl peroxide [e.g., Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

AND

3 - If the request is non-preferred*, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Absorica, Absorica LD, Amnesteem, Claravis, generic isotretinoin caps, Myorisan, Zenatane, Accutane	
Diagnosis	Persistent or Recurring Acne After 2 Months Off Therapy
Approval Length	5 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - After greater than or equal to 2 months OFF therapy, persistent or recurring severe recalcitrant nodular acne is still present	
Notes	Authorization will be given only by clinical pharmacist review for up to 5 months.

Product Name: Brand Absorica, Absorica LD, Amnesteem, Claravis, generic isotretinoin caps, Myorisan, Zenatane, Accutane	
Diagnosis	Dose Titration
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Confirmation that the cumulative dose is less than 150 mg/kg (milligrams/killogram) (there is little therapeutic benefit to be gained by increasing the cumulative dose beyond 150 mg/kg)*	
Notes	Authorization will be given only by clinical pharmacist review for 1 month to allow for titration up to the target dose. *See Background for dosing regimens.

2 . Background

Benefit/Coverage/Program Information

Dosing by Body Weight (based on administration with food):

Body Weight		Daily Dose		
Kg	Lbs	0.5 mg/kg/day	1 mg/kg/day	2 mg/kg/day
40	88	20	40	80
50	110	25	50	100
60	132	30	60	120
70	154	35	70	140
80	176	40	80	160
90	198	45	90	180
100	220	50	100	200

3 . Revision History

Date	Notes

6/6/2023	Updated GPI and product name lists, added Accutane and isotretinoin, removed table in Background, added PDL link in note, cleaned up criteria.

Isturisa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110647
Guideline Name	Isturisa
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Isturisa	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Cushing's disease

AND

1.2 ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name: Isturisa	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to Isturisa therapy

Product Name: Isturisa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Isturisa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Isturisa	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Isturisa therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Joenja (leniolisib)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127736
Guideline Name	Joenja (leniolisib)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Joenja	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)

AND

1.2 Molecular genetic testing confirms mutations in the PIK3CD or PIK3R1 gene

AND

1.3 BOTH of the following:

1.3.1 Presence of nodal and/or extranodal proliferation (e.g., lymphadenopathy, splenomegaly, hepatomegaly)

AND

1.3.2 Presence of other clinical findings and manifestations consistent with APDS (e.g., recurrent sino-pulmonary infections, bronchiectasis, enteropathy)

AND

1.4 Trial and failure, contraindication, or intolerance to at least ONE standard of care treatment for APDS [e.g., immunoglobulin replacement therapy, antimicrobial prophylaxis (e.g., azithromycin, bactrim), rituximab, tacrolimus, etc.]

AND

2 - Patient is 12 years of age or older

AND

3 - Patient weighs greater than or equal to 45 kg (kilograms)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Immunologist

Product Name: Joenja	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced lymph node size, increased naive B-cell percentage, decreased severity or frequency of infections/hospitalizations)

2 . Revision History

Date	Notes
7/7/2023	New guideline.

Juxtapid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110741
Guideline Name	Juxtapid
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment low density lipoprotein cholesterol (LDL-C) greater than 500 milligrams per deciliter

- Treated LDL-C greater than 300 milligrams per deciliter

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Patient has tried, failed or intolerant to Repatha and Praluent

AND

6 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

Notes	Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is continuing a low-fat diet and exercise regimen

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, low density lipoprotein [LDL] apheresis)

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Juxtapid therapy

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Jynarque

Prior Authorization Guideline

Guideline ID	GL-110575
Guideline Name	Jynarque
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)	

Product Name: Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Jynarque therapy	

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Kalydeco (ivacaftor)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136020
Guideline Name	Kalydeco (ivacaftor)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Kalydeco tabs/packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient has ONE of the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (see table in Background)

AND

3 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Kalydeco tabs/packet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Kalydeco therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Background

Benefit/Coverage/Program Information
CFTR Gene Mutations that are Responsive to Kalydeco

List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to KALYDE				
*711+3A→G **	*F311del*	*I148T*	*R75Q*	*S589N*
*2789+5G→A **	*F311L*	*I175V*	*R117C **	*S737F*
*3272-26A→G **	*F508C*	*I807M*	*R117G*	*S945L **
*3849+10kbC→T **	*F508C;S1251N † **	*I1027T*	*R117H **	*S977F **
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W **	*R170H*	*S1251N **
*A455E **	*G178R **	*L320V*	*R347H **	*S1255P **
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q **	*T1053I*
D110H	*G551D **	*L1480P*	*R553Q*	*V232D*
D192G	*G551S **	*M152V*	*R668C*	*V562I*
*D579G **	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
*D1152H **	*G1069R*	*P67L **	*R1070Q*	*W1282R*
D1270N	*G1244E **	*Q237E*	*R1070W **	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D **	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N **	
*E831X **	*H1375P*	*R74W*	*S549R **	

** Clinical data exist for these mutations.*

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations these exist independent of the presence of mutations on the other allele.

3 . Revision History

Date	Notes

11/7/2023	Added GPI for 5.8 mg packs

Katerzia, Norliqva (amlodipine oral solution)

Prior Authorization Guideline

Guideline ID	GL-125933
Guideline Name	Katerzia, Norliqva (amlodipine oral solution)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Katerzia, Norliqva	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 8 years of age or younger

OR

2 - BOTH of the following:

2.1 Requested medication is being used for ONE of the following diagnoses:

- Hypertension
- Chronic stable angina
- Confirmed or suspected vasospastic angina
- Angiographically documented Coronary Artery Disease (CAD)

AND

2.2 ONE of the following:

2.2.1 Trial and failure, contraindication, or intolerance to generic amlodipine tablets (verified via paid pharmacy claims or submitted chart notes)

OR

2.2.2 Patient is unable to swallow oral tablets/capsules

2 . Revision History

Date	Notes
5/22/2023	Updated criteria with age as a PA bypass.

Kerendia (finerenone)

Prior Authorization Guideline

Guideline ID	GL-126390
Guideline Name	Kerendia (finerenone)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

AND

2 - Urinary albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g (milligrams/gram)

AND

3 - Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m^2 (milliliters/minute/1.73 square meter)

AND

4 - Serum potassium level less than or equal to 5.0 mEq/L (milliequivalents/liter) prior to initiating treatment

AND

5 - ONE of the following:

5.1 Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with ONE of the following:

- Generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- Generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - ONE of the following:

2.1 Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB

OR

2.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

2 . Revision History

Date	Notes
6/7/2023	Updated all criteria sections.

Keveyis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64488
Guideline Name	Keveyis
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of primary hyperkalemic periodic paralysis or related variant

OR

1.2 Diagnosis of primary hypokalemic periodic paralysis or related variant

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Keveyis therapy	

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Kevzara

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125306
Guideline Name	Kevzara
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Kevzara	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g. chart notes) documenting ALL of the following:

1.1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.1.2 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 History of failure, contraindication, or intolerance to ALL of the following:(paid pharmacy claims may be used to confirm trials):

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.1.4 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Kevzara therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of moderately to severely active RA

AND

1.2.3 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Kevzara	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Kevzara 200 mg	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of polymyalgia rheumatica (PMR)

AND

2 - One of the following:

2.1 Patient has had an inadequate response to corticosteroids (e.g., prednisone)

OR

2.2 Patient cannot tolerate tapering of corticosteroids (e.g., prednisone)

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Kevzara 200 mg	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in symptoms (e.g., pain, stiffness) or lab values (e.g., C-reactive protein) from baseline
- Reduced need for corticosteroids (e.g., prednisone)

AND

2 - Prescribed by or in consultation with a rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

2 . Revision History

Date	Notes
5/5/2023	C&S to match AZM as of 6.1.23

Kineret

Prior Authorization Guideline

Guideline ID	GL-116076
Guideline Name	Kineret
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming the diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., Rheumatrex/Trexall [methotrexate], Arava [leflunomide], Azulfidine [sulfasalazine])

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- Humira (adalimumab)
- Xeljanz (tofacitinib)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Orencia (abatacept)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Kineret therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming the diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Diagnosis of NOMID has been confirmed by one of the following:

2.1 NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation

OR

2.2 Both of the following:

2.2.1 Two of the following clinical symptoms:

- Urticaria-like rash
- Cold/stress triggered episodes
- Sensorineural hearing loss
- Musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia)
- Chronic aseptic meningitis
- Skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing)

AND

2.2.2 Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Rheumatologist
- Pediatrician

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming the diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following:

- Nonsteroidal anti-inflammatory drug (NSAID) (e.g., Motrin [ibuprofen], Naprosyn [naproxen])
- Systemic glucocorticoid (e.g., prednisone)

Product Name: Kineret

Diagnosis	Rheumatoid Arthritis (RA), Neonatal-Onset Multisystem Inflammatory Disease (NOMID), Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Kineret therapy	

Product Name: Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) confirming the diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)	

2 . Revision History

Date	Notes
10/28/2022	Updated criteria, created new criteria for DIRA

Korlym

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64491
Guideline Name	Korlym
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of Endogenous Cushing's Syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 ONE of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

1.3 ONE of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of ONE of the following:

- Patient has improved glucose tolerance while on Korlym therapy
- Patient has stable glucose tolerance while on Korlym therapy

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Kuvan

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110614
Guideline Name	Kuvan
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Kuvan	
Diagnosis	Phenylketonuria (PKU)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)	

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

LAMA-LABA

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121164
Guideline Name	LAMA-LABA
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Bevespi Aerosphere, Stiolto Respimat, Anoro Ellipta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to treatment with a 30 day trial of a long-acting beta-agonist (e.g., Foradil, Serevent, Striverdi, Arcapta)

OR

2.2 History of failure, contraindication, or intolerance to treatment with a 30 day trial of an orally inhaled anticholinergic agent (e.g., Spiriva, Atrovent, Combivent, Tudorza)

AND

3 - If the request is for Bevespi, history of failure, contraindication, or intolerance to treatment with a 30 day trial of both of the following Preferred drugs:

- Anoro Ellipta
- Stiolto Respimat

2 . Revision History

Date	Notes
2/9/2023	Removed TD criteria section.

Lampit

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-78316
Guideline Name	Lampit
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Lampit	
Diagnosis	Chagas disease (American trypanosomiasis)
Approval Length	60 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Chagas disease (American trypanosomiasis) caused by Trypanosoma cruzi	

2 . Revision History

Date	Notes
12/15/2020	2021 Implementation

Lantidra (donislecel-jujn)

Prior Authorization Guideline

Guideline ID	GL-137406
Guideline Name	Lantidra (donislecel-jujn)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Lantidra	
Approval Length	30 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of Type 1 diabetes

AND

1.2 Patient is insulin dependent

AND

1.3 Patient is unable to approach target HbA1c (Hemoglobin A1c) because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education

AND

1.4 Patient has reduced awareness of hypoglycemia, as defined by the absence of adequate autonomic symptoms at glucose levels of less than 54 mg/dL (milligrams per deciliter)

AND

1.5 Patient has had at least one episode of severe hypoglycemia in the past 3 years with both of the following:

1.5.1 Patient required assistance of another person

AND

1.5.2 One of the following:

1.5.2.1 Symptoms were associated with a blood glucose level less than 50 mg/dL

OR

1.5.2.2 Prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration

AND

1.6 Patient will be on concomitant immunosuppression (e.g., daclizumab, sirolimus, tacrolimus, etanercept, mycophenolate mofetil, etc.)

AND **2** - Prescribed by or in consultation with an endocrinologist **AND** **3** - Patient has not had more than three infusions of Lantidra in their lifetime*

Notes	*There are no data regarding the effectiveness or safety for patients r eceiving more than three infusions.

Product Name: Lantidra	
Approval Length	30 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that patient has not achieved independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after previous infusion

AND

2 - Patient has not had more than three infusions of Lantidra in their lifetime*

Notes	*There are no data regarding the effectiveness or safety for patients r eceiving more than three infusions.

2 . Revision History

Date	Notes
12/6/2023	New guideline

Leqvio (inclisiran)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132878
Guideline Name	Leqvio (inclisiran)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following:

1.1.1 Both of the following:

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.1.2 One of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke

- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following:

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

- Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose
- Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - One of the following:

3.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Patient is unable to maintain adherence to proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor therapy

AND

5 - Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL for diagnosis of ASCVD

- LDL-C greater than or equal to 100 mg/dL for diagnosis of HeFH

AND

6 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

7 - Medication will not be used in combination with PCSK9 inhibitor therapy

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting LDL-C reduction from baseline while on therapy

AND

2 - One of the following:

2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - Medication will not be used in combination with PCSK9 inhibitor therapy

2 . Revision History

Date	Notes
9/11/2023	Update to account for 2022 ACC recommendations of a lower LDL th reshold of 55mg/dl for patients with ASCVD at very high risk

Leucovorin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110312
Guideline Name	Leucovorin
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Leucovorin tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Methotrexate toxicity prophylaxis

OR

1.2 Treatment of hematologic toxicity from folic acid antagonists (i.e., pyrimethamine toxicity treatment or trimethoprim toxicity treatment)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Lidocaine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118261
Guideline Name	Lidocaine
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Proxivol, Regenecare HA 2% gel, 7T Lido gel, lidocaine jelly 2%	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Used with catheters or open mucus membrane areas	

2 . Revision History

Date	Notes

12/12/2022	Updated guideline name, updated GPI and product name lists, remo ved lidocaine 4% and 5% oint, removed auto-denial criteria, cleaned up criteria.

Lidoderm (lidocaine) 5% patches

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118259
Guideline Name	Lidoderm (lidocaine) 5% patches
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brand Lidoderm patch, generic lidocaine 5% patch	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

2 . Revision History

Date	Notes
12/12/2022	New guideline

Livmarli (maralixibat)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124147
Guideline Name	Livmarli (maralixibat)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Livmarli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming BOTH of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene

AND

2 - Documentation of ONE of the following:

- Total serum bile acid > 3x the upper limit of normal (ULN)
- Conjugated bilirubin > 1 mg/dL (milligrams/deciliter)
- Fat soluble vitamin deficiency otherwise unexplainable
- Gammaglutamyl transpeptidase (GGT) > 3x ULN

AND

3 - Patient is experiencing moderate to severe cholestatic pruritus

AND

4 - Patient has had an inadequate response to at least TWO of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Patient is 3 months of age or older

AND

6 - Prescribed by or in consultation with a hepatologist

Product Name: Livmarli	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

2 . Revision History

Date	Notes
4/3/2023	Updated age criterion due to expanded age approval

Livtencity

Prior Authorization Guideline

Guideline ID	GL-116134
Guideline Name	Livtencity
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Livtencity	
Diagnosis	CMV infection/disease
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cytomegalovirus (CMV) infection/disease as confirmed by one of the following methods:

- quantitative polymerase chain reaction (qPCR)
- CMV pp65 antigenemia

AND

2 - Patient is a recipient of one of the following:

- Hematopoietic stem cell transplant
- Solid organ transplant

AND

3 - Trial and failure of a minimum 2 weeks duration, contraindication, or intolerance to one of the following therapies at an appropriately indicated dose:

- Intravenous (IV) ganciclovir
- Oral valganciclovir
- IV foscarnet
- IV cidofovir

AND

4 - Patient is 12 years of age or older

AND

5 - Patient weighs greater than or equal to 35kg

AND

6 - Prescribed by or in consultation with a provider who specializes in one of the following areas:

- Transplant
- Infectious Disease

2 . Revision History

Date	Notes
10/28/2022	Removed references and end note, no changes to clinical criteria.

Lodoco (colchicine)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136021
Guideline Name	Lodoco (colchicine)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Lodoco	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cardiovascular disease (CV)

AND

2 - Used for the secondary prevention of CV disease

AND

3 - Patient is on guideline therapy management for multiple risk factors (e.g., dyslipidemia, hypertension, hyperglycemia) associated with CV disease

AND

4 - Submission of medical records (e.g., chart notes) or paid claims documenting trial and failure or intolerance to colchicine 0.6 mg tablets

Product Name: Lodoco	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy(e.g., reduced risk of cardiovascular death, myocardial infarction, ischemia-driven coronoary revascularization)

2 . Revision History

Date	Notes
11/7/2023	New GL

Long-Acting Opioid Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116082
Guideline Name	Long-Acting Opioid Products
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: generic morphine sulfate ER tabs, Brand MS Contin, morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, Xtampza ER, Brand Conzip, generic tramadol ER biphasic release, generic tramadol ER, generic methadone, Brand Methadose, hydromorphone ER, hydrocodone ER caps	
Diagnosis	PA REQUIRED for use of MAT and other Opioids
Guideline Type	DUR
Approval Criteria **1** - Provider attests to notify the prescriber of the MAT (medication assisted treatment) therapy and the prescriber of the MAT therapy approves the concurrent opioid therapy	

AND

2 - The days supply does not exceed 14 days for a surgical procedure

AND

3 - The days supply does not exceed 5 days for all other requests

AND

4 - There has not been a previous approval in the last 6 months

Notes	Approval Length: 14 Days for surgical procedure, 5 Days for all other r equests

Product Name: generic morphine sulfate ER tabs, fentanyl patches 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tabs (non-biphasic release)	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be i ssued and a maximum 30 day authorization may be authorized one ti

	me for the requested drug/strength combination up to the requested q uantity for transition to an alternative treatment.

Product Name: Brand MS Contin, generic morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, generic methadone, Brand Methadose, hydromorphone ER, generic hydrocodone ER caps	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

AND

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 The patient has a history of failure, contraindication, or intolerance to a trial of at least THREE of the following (Document drugs and date of trials):*

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal patches (12 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg)**
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)

OR

2.1.2 Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care pain (Document date regimen was started)

AND

2.2 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr are non-preferred.

Product Name: Brand Conzip, generic tramadol ER biphasic release caps, generic tramadol ER biphasic release tabs	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

AND

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 The patient has a history of failure, contraindication or intolerance to a trial of BOTH of the following (Document drugs and date of trials):*

- tramadol immediate release (IR)
- tramadol extended release tablets (non-biphasic release tablets)

OR

2.1.2 Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care pain (Document date regimen was started)

AND

2.2 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *Claims history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: generic morphine sulfate ER tabs, fentanyl patches 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tabs (non-biphasic release)	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [Document drug(s) and date of trial]*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

2.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following:

3.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial)*

AND

3.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (Document drug and date of trial)*

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5 mcg/hr are non-preferred.

Product Name: Brand MS Contin, morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, generic methadone, Brand Methadose, hydromorphone ER, generic hydrocodone ER caps	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [Document drug(s) and date of trial]*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

2.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - The patient has a history of failure, contraindication, or intolerance to at least THREE of the following (Document drugs and date of trials):*

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal (12 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg)**
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)

AND

4 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following:

4.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial)*

AND

4.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (Document drug and date of trial)*

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5 mcg/hr are non-preferred.

Product Name: Brand Conzip, generic tramadol ER biphasic release caps, generic tramadol ER biphasic release tabs	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [Document drug(s) and date of trial]*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR **2.3** Postoperative pain is expected to be moderate to severe and persist for an extended period of time **AND** **3** - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following: **3.1** Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial)* **AND** **3.2** Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (Document drug and date of trial)* **AND** **3.3** The patient has a history of failure, contraindication, or intolerance to BOTH of the following (Document drugs and date of trials):* • tramadol immediate release (IR)** • tramadol extended release tablets (non-biphasic release tablets)**	
Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *If the request is for tramadol extended release capsules or tramadol extended release biphasic release tablets and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued and a maximum 30-day authorization may be author

	ized one time for the requested drug/strength combination up to the re quested quantity for transition to an alternative treatment. *Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **Drug may require prior authorization.

Product Name: generic morphine sulfate ER tabs, fentanyl patches 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tabs (non-biphasic release)	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic

• Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time) • Pain management is required around the clock with a long-acting opioid	
Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. **Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5m cg/hr are non-preferred.

Product Name: Brand MS Contin, morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, generic methadone, Brand Methadose, hydromorphone ER, generic hydrocodone ER caps	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. **Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr are non-preferred.

Product Name: Brand Conzip, generic tramadol ER biphasic release caps, generic tramadol ER biphasic release tabs	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *If the request is for tramadol extended release capsules or tramadol extended release biphasic release tablets and the patient is currently taking the requested long-acting opioid for at least 30 days and has m

	et the medical necessity authorization criteria requirements for treatm ent with an opioid, but has not tried the preferred alternatives a denial should be issued and a maximum 30-day authorization may be author ized one time for the requested drug/strength combination up to the re quested quantity for transition to an alternative treatment.

Product Name: generic morphine sulfate ER tabs, Brand MS Contin, morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, Xtampza ER, Brand Conzip, generic tramadol ER biphasic release, generic tramadol ER, generic methadone, Brand Methadose, hydromorphone ER, hydrocodone ER caps	
Guideline Type	Quantity Limit
Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (see Table 1 in the Background section)	
Notes	Authorization will be issued for: • Cancer pain/hospice/end-of-life related pain: 12 months • All Tramadol ER requests: 12 months • Non-cancer pain/non-hospice/non-end-of-life related pain: 6 months

Product Name: generic morphine sulfate ER tabs, Brand MS Contin, morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, Xtampza ER, Brand Conzip, generic tramadol ER biphasic release, generic tramadol ER, generic methadone, Brand Methadose, hydromorphone ER, hydrocodone ER caps	
Diagnosis	Doses Exceeding the Cumulative MME of 90 mg - Cancer/Hospice/End-of-Life/Palliative Care/Skilled Nursing Facility/Traumatic Injury Related Pain*
Approval Length	12 month(s)
Guideline Type	Morphine Milligram Equivalent (MME) MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit

Approval Criteria

1 - Doses exceeding the cumulative morphine milligram equivalent (MME) of 90 milligrams will be approved up to the requested amount for ALL opioid products if the patient has one of the following conditions:

- Active oncology diagnosis
- Hospice care
- End-of-life care (other than hospice)
- Palliative care
- Skilled nursing facility care
- Traumatic injury, including burns and excluding post-surgical procedure

AND

2 - Provider attests patient has been prescribed naloxone (may also be verified via paid pharmacy claims)

Notes	*Authorization will be issued for 12 months for one of the above conditions. The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased.

Product Name: generic morphine sulfate ER tabs, Brand MS Contin, morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, Xtampza ER, Brand Conzip, generic tramadol ER biphasic release, generic tramadol ER, generic methadone, Brand Methadose, hydromorphone ER, hydrocodone ER caps	
Diagnosis	Doses Exceeding the Cumulative MME of 90 mg - Non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalent (MME) MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- if used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - BOTH of the following:

2.1 Patient has tried and failed non-opioid pain medication (document drug name and date of trial)

AND

2.2 Opioid medication doses of less than 90 morphine milligram equivalent (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

AND

3 - Provider attests patient has been prescribed naloxone (may also be verified via paid pharmacy claims)

Notes	*If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested MME dose. **Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain up to the current requested MME plus 90 MME.

Product Name: generic morphine sulfate ER tabs, Brand MS Contin, morphine sulfate ER caps, morphine sulfate beads caps ER, fentanyl patches, generic hydrocodone ER tabs, Brand Hysingla ER, oxymorphone ER, Nucynta ER, generic oxycodone ER, Brand Oxycontin, Xtampza ER, Brand Conzip, generic tramadol ER biphasic release, generic tramadol ER, generic methadone, Brand Methadose, hydromorphone ER, hydrocodone ER caps	
Diagnosis	Doses Exceeding the Cumulative MME of 90 mg - Non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalent (MME)** MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- if used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

4 - Provider attests patient has been prescribed naloxone (may also be verified via paid pharmacy claims)	
Notes	*If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested MME dose. **Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain up to the current requested MME plus 90 MME.

2 . Background

Benefit/Coverage/Program Information

Table 1. CDC Recommended Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses	90 MME Equivalent (mg/day) (non treatment naïve)
Morphine	None	90mg
Morphine and naltrexone	None	90mg
Hydromorphone	None	22.5mg
Fentanyl transdermal, mcg/hr	None	37.5 mcg/hr
Hydrocodone	None	90mg
Methadone	None	Conversion factor is variable based upon dose
Tapentadol	500mg ER products	225mg
Oxymorphone	None	30mg
Oxycodone	Xtampza Only =288mg	60mg
Tramadol	300mg ER products	900mg

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

Max MME is the maximum dose per day based on morphine milligram equivalents allowed without consultation or prescription by a pain specialist. Max MME is based upon the CDC guidelines and adjusted for currently available product strengths. Fentanyl is dosed in mcg/hr rather than mg/day.

3 . Revision History

Date	Notes
10/26/2022	Cleaned up notes, added attestation criteria for naloxone requiremen t to 90 MME Exceeded sections.

Lonhala and Yupelri

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121176
Guideline Name	Lonhala and Yupelri
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Lonhala Magnair, Yupelri	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD)

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to Spiriva Handihaler (tiotropium)

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to use a metered-dose, dry powder, or slow mist inhaler (e.g., Spiriva Handihaler) to control his/her COPD due to ONE of the following:

2.2.1.1 Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)

OR

2.2.1.2 Patient is unable to generate adequate inspiratory force [e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 liters per minute]

AND

2.2.2 History of failure, contraindication, or intolerance to ipratropium nebulized solution (generic Atrovent)

Product Name: Lonhala Magnair, Yupelri	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes

2/9/2023	Removed TD criteria section.

Lucemyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124170
Guideline Name	Lucemyra
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Lucemyra	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For symptoms of abrupt opioid withdrawal

AND

2 - Opioids have been discontinued

AND

3 - BOTH of the following:

3.1 History of failure, contraindication, or intolerance to clonidine as verified by recent clonidine claims history in the past 180 days

AND

3.2 Lucemyra was initiated in the inpatient setting

AND

4 - Prescriber must verify patient has been screened for hepatic and renal impairment and that dosing is appropriate for the patient's degree of hepatic and renal function

AND

5 - Prescriber must verify patient's vital signs have been monitored and that the patient is capable of and has been instructed on self-monitoring for hypotension, orthostasis, bradycardia, and associated symptoms

AND

6 - Patient does not have severe coronary insufficiency, a recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia

AND

7 - Patient does not have congenital long QT syndrome

2 . Revision History

Date	Notes
4/6/2023	Removed note regarding approval duration

Lumizyme

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-65778
Guideline Name	Lumizyme
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Lumizyme	
Diagnosis	Pompe disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency)	

2 . Revision History

Date	Notes
4/27/2020	Removed Myozyme from title

Lupkynis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134720
Guideline Name	Lupkynis
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Lupkynis	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Provider attests to ONE of the following:

- Diagnosis is biopsy proven
- Biopsy is contraindicated in the patient

AND

3 - Provider attests to ONE of the following:

3.1 Clinical progression (e.g., worsening of proteinuria or serum creatinine) after 3 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

OR

3.2 Failure to respond after 6 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

AND

4 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

5 - Patient is NOT receiving Lupkynis in combination with either of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

6 - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

Product Name: Lupkynis	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lupkynis therapy

AND

2 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

3 - Patient is NOT receiving Lupkynis in combination with either of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

4 - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

AND

5 - ONE of the following:

5.1 Patient has been on Lupkynis therapy for less than 12 months

OR

5.2 BOTH of the following:

5.2.1 Patient has completed 12 or more months of Lupkynis therapy

AND

5.2.2 The provider attests that the benefit of continuation of therapy exceeds the risk in light of the patient's treatment response and risk of worsening nephrotoxicity

Luxturna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135517
Guideline Name	Luxturna
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Luxturna	
Approval Length	45 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is greater than 12 months of age

AND

2 - Diagnosis of a confirmed biallelic RPE65 mutation-associated retinal dystrophy [e.g.,

Leber's congenital amaurosis (LCA), retinitis pigmentosa (RP), early onset severe retinal dystrophy (EOSRD), etc.] **AND** **3** - Genetic testing documenting biallelic mutations of the RPE65 gene **AND** **4** - Sufficient viable retinal cells as determined by optical coherence tomography (OCT) confirming an area of retina within the posterior pole of greater than 100 micrometers thickness **AND** **5** - Prescribed and administered by ophthalmologist or retinal surgeon with experience providing sub-retinal injections **AND** **6** - Patient has not previously received Luxturna treatment in the intended eye **AND** **7** - Must not exceed more than 1 treatment per lifetime per eye	
Notes	Authorization will be issued for no more than 1 treatment per lifetime per eye and for no longer than 45 days from approval.

2 . Revision History

Date	Notes
10/30/2023	Updated guideline name, updated approval length, added once per lifetime criteria and note.

Lyrica

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110292
Guideline Name	Lyrica
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Lyrica	
Diagnosis	Seizure Disorder
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizure disorder

AND

2 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

Product Name: Brand Lyrica	
Diagnosis	Neuropathic Pain Associated with Spinal Cord Injury
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuropathic pain associated with spinal cord injury

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Fibromyalgia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fibromyalgia

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Diabetic peripheral neuropathy (DPN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Post herpetic neuralgia (PHN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post herpetic neuralgia (PHN)

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Lyrica CR	
Diagnosis	Diabetic peripheral neuropathy (DPN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2 - History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800 milligrams daily for 4 weeks

AND

3 - History of failure, contraindication, or intolerance to treatment with ONE of the following:

- Tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks, or intolerance to a tricyclic antidepressant
- Serotonin and norepinephrine reuptake inhibitor (SNRI) antidepressant (i.e. duloxetine, venlafaxine)

AND

4 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

Product Name: Lyrica CR	
Diagnosis	Post herpetic neuralgia (PHN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post herpetic neuralgia (PHN)

AND

2 - History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800 milligrams daily for 4 weeks

AND

3 - History of failure, contraindication, or intolerance to a tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks

AND

4 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Lysteda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64383
Guideline Name	Lysteda
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Lysteda, generic tranexamic acid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cyclic heavy menstrual bleeding	

2 . Revision History

Date	Notes

3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137446
Guideline Name	Lyvispah (baclofen granules), Ozobax-Ozobax DS (baclofen oral solution)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Lyvispah, Ozobax, Ozobax DS	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure, or intolerance to baclofen tablets

OR

2 - Patient is unable to swallow oral tablets

2 . Revision History

Date	Notes
12/7/2023	Updated guideline name. Added Ozobax/Ozobax DS. Added bypass for pts who cannot swallow oral tablets/swallowing disorder.

Makena

Prior Authorization Guideline

Guideline ID	GL-116662
Guideline Name	Makena
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Brand Makena*, generic hydroxyprogesterone caproate*	
Guideline Type	Prior Authorization

Approval Criteria

1 - Current singleton pregnancy

AND

2 - History of a prior spontaneous preterm birth of a singleton pregnancy

AND **3** - Treatment is initiated between 16 weeks, 0 days of gestation and 20 weeks, 6 days of gestation **AND** **4** - Administration is to continue weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first **AND** **5** - If the request is for generic hydroxyprogesterone caproate, the patient has a history of failure, contraindication or intolerance to Brand Makena

Notes	*Approval duration is up to 21 weeks; approval duration should take in to account gestation week when Makena will be started and only auth orized up to week 37.

2 . Revision History

Date	Notes
11/7/2022	Updated gestational days for drug initiation to align w PI

Marinol, Syndros

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110298
Guideline Name	Marinol, Syndros
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Marinol, Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to formulary generic dronabinol

OR

2.2 Patient is unable to swallow capsules

AND

3 - History of failure, contraindication, or intolerance to a 5HT-3 (5-hydroxytriptamine) receptor antagonist [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

AND

4 - History of failure, contraindication, or intolerance to ONE of the following:

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Generic Dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - History of failure, contraindication, or intolerance to a 5HT-3 (5-hydoxytriptamine) receptor antagonist [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

AND

3 - History of failure, contraindication, or intolerance to ONE of the following:

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Brand Marinol, Syndros	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

- Patient is less than 65 years of age
- History of failure, contraindication, or intolerance to Megace (megestrol)

AND

4 - ONE of the following:

4.1 History of failure, contraindication, or intolerance to formulary generic dronabinol

OR

4.2 Patient is unable to swallow capsules

Product Name: Generic dronabinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

- Patient is less than 65 years of age
- History of failure, contraindication, or intolerance to Megace (megestrol)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Mavenclad

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110615
Guideline Name	Mavenclad
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Mavenclad	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary progressive MS with relapses)

AND

2 - Prescribed by, or in consultation with, a specialist in the treatment of MS (e.g., neurologist)

AND

3 - ONE of the following:

3.1 Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to TWO of the following disease-modifying therapies for MS (document medication used, dose, and duration):

- Interferon beta-1a (Avonex, Rebif)
- Interferon beta-1b (Betaseron, Extavia)*
- Peginterferon beta-1a (Plegridy)
- Glatiramer acetate products (e.g., Copaxone, Glatopa)*
- A preferred dimethyl fumarate product (e.g., Tecfidera)
- Aubagio (teriflunomide)
- Gilenya (fingolimod)
- Mayzent (siponimod)
- Tysabri (natalizumab)**
- Ocrevus (ocrelizumab)**
- Lemtrada (alemtuzumab)**
- Zeposia (ozanimod)*
- Kesimpta (ofatumumab)*
- Bafiertam (monomethyl fumarate)*

OR

3.2 Patient is currently on Mavenclad

AND

4 - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

Notes	*Copaxone 40mg, Glatopa 20mg, glatiramer acetate, Bafiertam, Kesi mpta, Zeposia, and Extavia are non-preferred and should not be inclu ded in denial to provider. **Tysabri, Ocrevus, and Lemtrada are medical benefit and should not be included in denial to provider.

Product Name: Mavenclad	
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mavenclad treatment

AND

2 - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

AND

3 - Patient has not exceeded the FDA (Food and Drug Administration)-recommended limit of 2 treatment courses (4 treatment cycles) of Mavenclad

Notes	Duration of coverage will be limited to 1 reauthorization to allow 2 cum ulative treatment courses (4 treatment cycles) of Mavenclad therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Mepron

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110313
Guideline Name	Mepron
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Mepron, generic atovaquone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 The patient has a diagnosis (e.g. human immunodeficiency virus [HIV]) warranting Pneumocystis jirovecii pneumonia (PCP) infection prophylaxis

AND

1.1.2 The patient has a documented intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) and dapsone

OR

1.2 BOTH of the following:

1.2.1 The patient has a diagnosis of mild to moderate pneumonia caused by P. jirovecii

AND

1.2.2 The patient has a documented intolerance, contraindication, or history of treatment failure to TMP-SMX

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Metformin Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115891
Guideline Name	Metformin Products
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: generic metformin 625 mg immediate-release tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of greater than or equal to 12 week trial of preferred metformin immediate-release products	

Product Name: generic metformin extended-release (generic for Fortamet and generic for Glumetza)	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR)

AND

1.2 ONE of the following:

1.2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.3 History of greater than or equal to 12 week trial of metformin immediate-release

AND

1.4 One of the following:

1.4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release, in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

Product Name: Brand Glumetza, Brand Fortamet	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR)

AND

1.2 ONE of the following:

1.2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.3 History of greater than or equal to 12 week trial of metformin extended-release (generic Fortamet)

AND

1.4 One of the following:

1.4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Fortamet) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.5 History of greater than or equal to 12 week trial of metformin immediate-release

AND

1.6 One of the following:

1.6.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release, in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.6.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.7 Submission of article(s) published in the peer-reviewed medical literature showing that

the requested drug is likely to be more efficacious to this patient than metformin extended-release (generic Glucophage XR)

Miebo (perfluorohexyloctane ophthalmic solution)

Prior Authorization Guideline

Guideline ID	GL-132929
Guideline Name	Miebo (perfluorohexyloctane ophthalmic solution)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Miebo	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of dry eye disease confirmed by ONE of the following diagnostic tests:

- Schirmer test
- Ocular surface dye staining (e.g., rose bengal, fluorescein, lissamine green)
- Tear function index/fluorescein clearance test
- Tear break up time

- Tear film osmolarity
- Slit lamp lid evaluation
- Lacrimal gland function

AND

2 - Trial and failure, contraindication, or intolerance to at least one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments)

AND

3 - Trial and failure, contraindication, or intolerance to Restasis

AND

4 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

Product Name: Miebo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

2 . Revision History

Date	Notes

9/12/2023	New guideline

Migranal

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-133817
Guideline Name	Migranal
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Brand Migranal, generic dihydroergotamine mesylate	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - History of failure, contraindication, or intolerance to TWO preferred 5-HT1 (5-

hydroxytryptamine-1) receptor agonist (triptan) alternatives [e.g., Imitrex (sumatriptan), Maxalt or Maxalt-MLT (rizatriptan)]

2 . Revision History

Date	Notes
9/26/2023	Removed QL section, cleaned up criteria.

Monurol

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110297
Guideline Name	Monurol
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Monurol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The provider has submitted labs showing the culture and sensitivity is positive for Monural and negative to Ciprofloxacin or Nitrofurantoin

OR

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

- Ciprofloxacin
- Nitrofurantoin

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Mozobil

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64499
Guideline Name	Mozobil
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Mozobil	
Approval Length	4 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Patients with non-Hodgkin's lymphoma (NHL) who will be undergoing autologous hematopoietic stem cell (HSC) transplantation
- Patients with multiple myeloma (MM) who will be undergoing autologous HSC transplantation

AND **2** - Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Zarxio (filgrastim)] **AND** **3** - Prescribed by, or in consultation with, a hematologist/oncologist	
Notes	*Authorization will be issued for 1 course of therapy (up to four days of therapy).

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

MS Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-122958
Guideline Name	MS Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Gilenya, Brand Gilenya, Brand Copaxone, Glatopa, Avonex Pen, Avonex, Rebif Rebidose, Rebif Rebidose Titration Pack, Rebif, Rebif Titration Pack, Betaseron, Extavia, generic fingolimod, generic glatiramer	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to a trial of ONE of the preferred* alternatives:

- Interferon Beta-1B (Extavia)
- Generic fingolimod 0.5 mg (milligram) capsule or Brand Gilenya 0.25 mg capsule
- Interferon Beta-1A (Rebif, Avonex)

AND

3 - If the request is for generic glatiramer 20 mg or Glatopa 20 mg, patient must have tried and failed Brand Copaxone 20 mg

AND

4 - If the request is for generic glatiramer 40 mg or Brand Copaxone 40 mg, patient must have tried and failed Glatopa 40 mg

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP *Preferred drug may require PA.

Product Name: Vumerity, Bafiertam, Kesimpta, Brand Tecfidera Starter Pack, Brand Tecfidera, Plegridy, Plegridy Starter Pack, Aubagio, Mayzent Starter Pack, Mayzent, generic dimethyl fumarate starter pack, generic dimethyl fumarate	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least TWO of the preferred* alternatives:

- Interferon Beta-1B (Extavia)
- Fingolimod (Gilenya)
- Brand Copaxone 20 mg
- Glatopa 40 mg
- Interferon Beta-1A (Rebif, Avonex)

Notes	*Preferred drug may require PA.

Product Name: Tascenso ODT	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient has a history of failure, contraindication, or intolerance to Gilenya*

Notes	*Preferred drug may require PA.

Product Name: Gilenya, Brand Gilenya, Brand Copaxone, Glatopa, Avonex Pen, Avonex, Rebif Rebidose, Rebif Rebidose Titration Pack, Rebif, Rebif Titration Pack, Betaseron, Extavia, generic glatiramer, Vumerity, Bafiertam, Kesimpta, Brand Tecfidera Starter Pack, Brand Tecfidera, Plegridy, Plegridy Starter Pack, Aubagio, Mayzent Starter Pack, Mayzent, Tascenso ODT, generic fingolimod, generic dimethyl fumarate starter pack, generic dimethyl fumarate	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/10/2023	Updated product name lists, combined first two criteria sections and added PDL link to note, updated T/F criteria.

Multaq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64388
Guideline Name	Multaq
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Multaq	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of ONE of the following:

- Paroxysmal Atrial Fibrillation (AF)

- Persistent AF defined as AF less than 6 months duration

AND

1.1.2 ONE of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

AND

1.1.3 Patient does not have New York Heart Association (NYHA) Class IV heart failure

AND

1.1.4 Patient does not have symptomatic heart failure with recent decompensation requiring hospitalization

OR

1.2 For continuation of current therapy

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Myalept

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110616
Guideline Name	Myalept
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Congenital generalized lipodystrophy associated with leptin deficiency
- Acquired generalized lipodystrophy associated with leptin deficiency

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

AND

4 - Documentation demonstrates that patient has at least ONE of the following:

4.1 Diabetes mellitus or insulin resistance with persistent hyperglycemia (hemoglobin A1C greater than 7.0%) despite BOTH of the following:

- Dietary intervention
- Optimized insulin therapy at maximum tolerated doses

OR

4.2 Persistent hypertriglyceridemia (triglycerides greater than 250 milligrams per deciliter) despite BOTH of the following:

- Dietary intervention
- Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Myalept therapy

AND **2** - Used as an adjunct to diet modification **AND** **3** - Prescribed by an endocrinologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Myfembree, Oriahnn

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120992
Guideline Name	Myfembree, Oriahnn
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)	

AND

2 - Patient is premenopausal

AND

3 - One of the following:

3.1 History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:

- Combination (estrogen/progestin) contraceptive
- Progestins
- Tranexamic acid

OR

3.2 Patient has had a previous interventional therapy to reduce bleeding

AND

4 - Treatment duration of therapy has not exceeded a total of 24 months

Product Name: Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.)

AND

2 - Treatment duration of therapy has not exceeded a total of 24 months

Product Name: Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - One of the following:

3.1 History of inadequate pain control response following a trial of 30 days, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) contraceptive
- Progestins

OR

3.2 Patient has had surgical ablation to prevent recurrence

AND

4 - Treatment duration of Myfembree has not exceeded a total of 24 months

Product Name: Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain)

AND

2 - Treatment duration of Myfembree has not exceeded a total of 24 months

2 . Revision History

Date	Notes
2/9/2023	Moved guideline to standard formulary. Added Oriahnn. Added criteri a for Myfembree - for Endometriosis pain.

Mytesi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64389
Guideline Name	Mytesi
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Mytesi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) associated diarrhea	

2 . Revision History

Date	Notes

3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Nadolol

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110858
Guideline Name	Nadolol
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: generic nadolol	
Diagnosis	PA required for patients 18 years of age or older
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to 3 of the following:

- atenolol
- atenolol/chlorthalidone
- bisoprolol fumarate
- bisoprolol/hydrochlorothiazide
- carvedilol

- labetalol HCl
- metoprolol succinate
- metoprolol tartrate
- metoprolol/hydrochlorothiazide
- propranolol HCl
- propranolol/hydrochlorothiazide
- sotalol HCl

2 . Revision History

Date	Notes
8/10/2022	C&S to match AZM 10.1.22

Namzaric

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110808
Guideline Name	Namzaric
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Namzaric	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 History of BOTH of the following:

1.1.1 Memantine (generic Namenda)

AND

1.1.2 Donepezil (generic Aricept)

AND

1.2 Patient is stabilized on 10mg of donepezil once daily

2 . Revision History

Date	Notes
8/5/2022	C&S to match AZM 10.1.22

Natpara

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64500
Guideline Name	Natpara
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Natpara	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism

AND

1.2 25-hydroxy vitamin D level is above the lower limit of the normal laboratory reference range

AND

1.3 Patient is currently on active vitamin D (calcitriol) therapy

AND

1.4 Total serum calcium level (albumin corrected) is above 7.5 milligrams per deciliter

AND

2 - ONE of the following:

2.1 Patient is currently on calcium supplementation of 1-2 grams per day of elemental calcium in divided doses

OR

2.2 Patient has a contraindication to calcium supplementation

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Product Name: Natpara	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 9 milligrams per deciliter)

AND

2 - Patient continues to take concomitant calcium supplementation that is sufficient to meet daily requirements

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Nayzilam and Valtoco

Prior Authorization Guideline

Guideline ID	GL-110315
Guideline Name	Nayzilam and Valtoco
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epilepsy

AND

2 - Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

Product Name: Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Valtoco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epilepsy

AND

2 - Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

AND

4 - One of the following:

4.1 Patient is less than 12 years of age

OR

4.2 History of failure, contraindication, or intolerance to Nayzilam

Product Name: Valtoco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Nexiclon XR (clonidine ER)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126395
Guideline Name	Nexiclon XR (clonidine ER)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Nexiclon XR, Brand Clonidine ER 24HR 0.17 mg tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication is being used for treatment of hypertension

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following (verified via paid pharmacy claims or submitted chart notes):

- generic clonidine oral tablet
- generic clonidine topical patch

2 . Revision History

Date	Notes
6/7/2023	Added brand clonidine ER 24Hr GPI and product name, updated crit eria.

Nexletol, Nexlizet

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134019
Guideline Name	Nexletol, Nexlizet
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD)

AND

2 - ONE of the following:

2.1 Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e., atorvastatin 40-80 mg (milligrams), rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK [creatine kinase] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate- intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] statin therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK [creatine kinase] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following LDL-C (low-density lipoprotein cholesterol) values while on maximally tolerated statin therapy within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL (milligrams/deciliter) with ASCVD
- LDL-C greater than or equal to 100 mg/dL without ASCVD

AND

4 - ONE of the following:

4.1 Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy

OR

4.2 Patient has a history of contraindication or intolerance to ezetimibe

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at maximally tolerated dose (unless patient has documented inability to take lipid-lowering therapy)

2 . Revision History

Date	Notes
9/29/2023	Updated criteria to remove documentation verbiage from statin contr aindication, changed statin verbiage, cleaned up criteria.

Nityr

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110617
Guideline Name	Nityr
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Nityr	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary tyrosinemia type 1

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use Orfadin (nitisinone) capsules or suspension

Product Name: Nityr	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient shows evidence of positive clinical response (e.g. decrease in urinary/plasma succinylacetone and alpha-1-microglobulin levels) while on Nityr therapy	

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Nocdurna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-81643
Guideline Name	Nocdurna
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Nocdurna	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

AND

2 - Patient wakes at least twice per night on a reoccurring basis to void

AND

3 - Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months

AND

4 - The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes [e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure]

AND

5 - Prescriber attests that the risks have been assessed and benefits outweigh the risks

Product Name: Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient has routine monitoring for serum sodium levels

AND

3 - Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

2 . Revision History

Date	Notes
3/1/2021	Noctiva removed from the guideline

Non-Preferred Drugs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-122006
Guideline Name	Non-Preferred Drugs
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/3/2023

1 . Criteria

Product Name: Non-Preferred Drugs	
Approval Length	12 months*
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following**:

1.1.1 If there are at least three preferred alternatives, history of trial per patient's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to at least THREE preferred alternatives [Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request]

OR

1.1.2 If there are fewer than three preferred alternatives, the patient must have a history of trial per patient's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the preferred products (Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)

OR

1.1.3 There are no preferred formulary alternatives for the requested drug

AND

1.2 If the request is for a multi-source brand medication (i.e., MSC O), ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 The brand is being requested because of an adverse reaction, allergy, or sensitivity to the generic and the prescriber must attest to submitting the FDA (Food and Drug Administration) MedWatch Form for allergic reactions to the medications

AND

1.2.1.2 If there are generic product(s), the patient has tried at least three (if available)

OR

1.2.2 ONE of the following:

- The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure)
- The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided)
- Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the patient (rationale must be provided)

AND

1.3 ONE of the following:

1.3.1 The requested drug must be used for an FDA-approved indication

OR

1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- The requested drug must be used for an FDA-approved indication
- FDA approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential patient outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data, and pharmacoeconomic studies
- Other drug reference resources

AND

1.4 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program***

OR

2 - If the requested medication is a behavioral health medication, ONE of the following:

- The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

• The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge	
Notes	*Anti-infectives: Approve for the requested time frame, or if duration is not specified approve the request for 30 days. *Controlled Substances shall be approved for the requested time. If th ere is not a requested time period and it is not clear in the directions, approve for one time only. *Other medications: Approved for the requested time frame, or if durat ion is not specified, approve for 12 months. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/ariz ona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UH CCP ***Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, or sexual dys function purposes are NOT medically accepted indications and are N OT recognized as a covered benefit. Erectile dysfunction drugs (Cialis /Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
3/3/2023	Removed Non-Preferred Generics (MSC Y) note per PAM and PA te am request.

Non-Preferred Prenatal Vitamins

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110339
Guideline Name	Non-Preferred Prenatal Vitamins
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Non-Preferred Prenatal Vitamins	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of failure, contraindication, or intolerance to ALL of the following preferred products:*	
Notes	*Please refer to the background table for the alternatives

2 . Background

Benefit/Coverage/Program Information

Preferred Products:

GPI-14	Product ID	Product Label	GPI-14 Description
78512000000315	73317105009	PRENATVITE TAB RX	*PRENATAL MULTIVITAMINS & MINERALS W/IRON & FA TAB 0.8 MG***
78512010000330	69543026790	PNV TABS TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	60258019309	PRENATABS RX TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070510	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070516	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070518	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	58657013390	THRIVITE RX TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	71186001924	VIL-RX TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	13811051690	VOL-TAB RX TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000352	13811002710	ELITE-OB TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 50-1.25 MG***
78512010000352	68025001010	OB COMPLETE TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 50-1.25 MG***
78512015000324	58657017001	M-NATAL PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	12830080001	M-VIT TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	70898022001	NEONATAL TAB COMPLTE	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	70898011501	NEONATAL PLS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***

78512015000324	75834005001	NIVA-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	00813931601	O-CAL FA TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	71399624609	ONE VITE TAB 1MG PLUS	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	39328010610	PRENATAL TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	39328010650	PRENATAL TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	63044015001	PRENATAL VIT TAB LOW IRON	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	63044015005	PRENATAL VIT TAB LOW IRON	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69543025810	PREPLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69543025850	PREPLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	67112010100	TRICARE TAB PRENATAL	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	17139080030	VITATHELY TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	13811051910	VOL-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	13811051950	VOL-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69367026701	WESTAB PLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000329	60258019201	TRINATE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 28-1 MG***
78512015000329	13811051410	VOL-NATE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 28-1 MG***
78512015000332	10267227001	CO-NATAL FA TAB 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***

78512015000332	73317828601	NEONATAL TAB COMPLETE	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***
78512015000332	69543025910	PRETAB TAB 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***
78512015000360	13811000710	TRINATAL RX TAB 1	*PRENATAL VIT W/ FE FUMARATE-FA TAB 60-1 MG***
78512015000360	51991056601	VINATE ONE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 60-1 MG***
78512015000366	58607081120	MYNATAL PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000366	58607010565	MYNATAL-Z TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000366	00642007912	VITAFOL-OB TAB 65-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000530	13811001490	COMPLETENATE CHW	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070710	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070716	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070718	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	60258019701	PRENATAL 19 CHW TAB	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	13925011701	SE-NATAL 19 CHW	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512016000130	13811004930	ULTIMATECARE CAP ONE	*PRENATAL VIT W/ FE CBN-FE ASP GLYC-FA-OMEGA 3 CAP 27-1MG***

78512018000116	23359010530	C-NATE DHA CAP 28-1-200	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	23359020030	RELNATE DHA CAP	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	69543037030	VIRT-NATE CAP DHA	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	64661008030	VIVA DHA CAP	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512022000320	69543024190	VIRT-PN TAB	*PRENATAL VIT W/ FE FUM-METHYLFOLATE-FA TAB 27-0.6-0.4 MG***
78512046000330	55495012501	ATABEX OB TAB 29-1MG	*PRENATAL VIT W/ FE BISGLYCINATE CHELATE-FA TAB 29-1 MG***
78512046000330	51991017801	VINATE II TAB	*PRENATAL VIT W/ FE BISGLYCINATE CHELATE-FA TAB 29-1 MG***
78512051000327	00178085890	CITRANATAL TAB RX	*PRENATAL W/O A W/ FE CARBONYL-FE GLUC-DSS-FA TAB 27-1MG***
78512058000150	52747062030	CONCEPT OB CAP	*PRENATAL W/O A W/FE FUM-FE POLY-FA CAP 130-92.4-1 MG***
78512058000150	13811053530	FOLIVANE-OB CAP	*PRENATAL W/O A W/FE FUM-FE POLY-FA CAP 130-92.4-1 MG***
78512060000325	51991015501	VINATE M TAB	*PRENATAL VIT W/ SEL-FE FUMARATE-FA TAB 27-1 MG***
78512070000330	42937070610	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	42937070616	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	42937070618	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	13925011601	SE-NATAL 19 TAB	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***

78512091000135	52747062130	CONCEPT DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	58657012130	DOTHELLE DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	13811053630	TARON-C DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	76439033130	VIRT-C DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78516020006330	00642007630	VITAFOL-OB PAK +DHA	*PRENATAL MV W/FE FUM-FA TAB 65-1 MG & DHA CAP 250 MG PACK *
78516032000130	00642007030	VITAFOL-ONE CAP	*PRENATAL MV W/ FE POLYSAC CMPLX-FA-DHA CAP 29-1-200 MG***
78516032006325	00642007530	SELECT-OB+ PAK DHA	*PRENATAL MV W/FE POLY-FA CHW 29-1 MG & DHA CAP 250 MG PAK *

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Northera

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110618
Guideline Name	Northera
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Northera	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) as defined by ONE of the following when an upright position is assumed or when using a head-up tilt-table testing at an angle of at least 60 degrees:

- At least a 20 millimeters of mercury (mm Hg) fall in systolic pressure
- At least a 10 mm Hg fall in diastolic pressure

AND

2 - nOH caused by ONE of the following:

- Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure)
- Dopamine beta-hydroxylase deficiency
- Non-diabetic autonomic neuropathy

AND

3 - Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy)

AND

4 - The patient has tried at least TWO of the following non-pharmacologic interventions:

- Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]
- Raising the head of the bed 10 to 20 degrees
- Compression garments to the lower extremities or abdomen
- Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise)
- Increased salt and water intake, if appropriate
- Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing)

AND

5 - No previous diagnosis of supine hypertension

AND

6 - Prescribed by, or in consultation with, ONE of the following specialists:

- Cardiologist
- Neurologist

- Nephrologist

AND

7 - History of failure (after a trial of at least 30 days), contraindication or intolerance to BOTH of the following medications:

- Florinef (fludrocortisone)
- ProAmatine (midodrine)

Product Name: Northera	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Northera therapy

AND

2 - Physiological countermeasures for neurogenic orthostatic hypotension (nOH) continue to be employed

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Nourianz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64392
Guideline Name	Nourianz
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Nourianz	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson’s disease

AND

2 - Used as adjunctive treatment to levodopa/carbidopa in patients experiencing “off” episodes

AND

3 - History of failure, contraindication, or intolerance to TWO anti-Parkinson’s disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

Product Name: Nourianz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nourianz therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Nucala (mepolizumab)

Prior Authorization Guideline

Guideline ID	GL-110603
Guideline Name	Nucala (mepolizumab)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by one of the following:

- Baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter
- Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months

OR

3.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications (verified via paid pharmacy claims):

4.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 6 years

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) [C]

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications (verified via paid pharmacy claims)

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone)

AND

3 - Used in combination with another agent for CRSwNP

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS; 0-10 scale])

AND

2 - Used in combination with another agent for CRSwNP

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

AND

2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone)

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., increase in remission time)

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient has been diagnosed for at least 6 months

AND

3 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

4 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

5 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

6 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

7 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Hematologist

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

2 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000

Beclometasone dipropionate (pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	200		400
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Nuedexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64393
Guideline Name	Nuedexta
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Nuedexta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pseudobulbar affect (PBA)	

2 . Revision History

Date	Notes

3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Nuplazid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64394
Guideline Name	Nuplazid
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson’s disease

AND

2 - Patient is currently experiencing hallucinations and delusions associated with Parkinson’s

disease psychosis (i.e., hallucination and delusion symptoms started after Parkinson's disease diagnosis)

Product Name: Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Nuplazid therapy	

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Nuzyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110334
Guideline Name	Nuzyra
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Nuzyra	
Diagnosis	Community-Acquired Bacterial Pneumonia
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 ALL of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

1.3.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics or antibiotic regimens:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name: Nuzyra	
Diagnosis	Acute Bacterial Skin and Skin Structure Infections
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 ALL of the following:

1.3.1 ONE of the following diagnoses:

1.3.1.1 BOTH of the following:

- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

1.3.1.2 BOTH of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

AND

1.3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.3.3 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

OR

1.4 ALL of the following:

1.4.1 Diagnosis of acute bacterial skin and skin structure infections

AND

1.4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

1.4.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics:

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

Product Name: Nuzyra	
Diagnosis	Off-Label Uses*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR **1.3** The medication is being prescribed by or in consultation with an infectious disease specialist.	
Notes	*Note: Authorization duration based on provider treatment durations, not to exceed 6 months.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

OAB - Overactive Bladder Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124175
Guideline Name	OAB - Overactive Bladder Agents
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Brand Enablex, generic darifenacin ER, Brand Ditropan XL, flavoxate, Gelnique, Gemtesa, Myrbetriq tab, Myrbetriq granules, Oxybutynin Chloride sol, Oxytrol (Rx), trospium, trospium ER, Brand Vesicare, generic solifenacin, Vesicare LS, generic oxybutynin 2.5mg IR tablet	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a history of failure, contraindication, or intolerance to a trial of THREE preferred products

- oxybutynin (generic Ditropan) 5mg tablet
- oxybutynin ER (generic Ditropan XL)
- Brand Detrol

- Brand Detrol LA
- Brand Toviaz

AND

2 - For oxybutynin solution requests ONLY, patient must have intolerance to the preferred alternative oxybutynin syrup

2 . Revision History

Date	Notes
4/7/2023	Added oxybutynin 2.5 mg tablet as NP drug. Specified preferred prer equisite option for all NPD is oxybutynin 5 mg IR tablet.

Ocaliva

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110619
Guideline Name	Ocaliva
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis (aka primary biliary cirrhosis)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid(e.g., Urso, ursodiol)

AND

2.1.2 Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

2.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

3 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Ocaliva therapy) while on Ocaliva therapy

AND

2 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Octreotide Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121030
Guideline Name	Octreotide Products
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Brand Sandostatin, generic octreotide, octreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - ONE of the following:

2.1 Inadequate response to ONE of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - If the request is for Brand Sandostatin, trial and failure, or intolerance to generic octreotide

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - ONE of the following:

2.1 Inadequate response to ONE of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Patient has responded to and tolerated treatment with generic octreotide or lanreotide

Product Name: Brand Sandostatin, generic octreotide, octreotide, Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy [e.g., reduction or normalization of IGF-1/GH (insulin-like growth factor-1/growth hormone) level for same age and sex, reduction in tumor size]

Product Name: Brand Sandostatin, generic octreotide, octreotide	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - If the request is for Brand Sandostatin, trial and failure, or intolerance to generic octreotide

Product Name: Brand Sandostatin, generic octreotide, octreotide	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea or flushing episodes

Product Name: Brand Sandostatin, generic octreotide, octreotide	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - If the request is for Brand Sandostatin, trial and failure, or intolerance to generic octreotide

Product Name: Brand Sandostatin, generic octreotide, octreotide	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea episodes

2 . Revision History

Date	Notes
2/7/2023	Updated product name lists, spelled out acronym, and updated T/F c riteria.

Ojjaara (momelotinib)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137434
Guideline Name	Ojjaara (momelotinib)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Ojjaara	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of one of the following:

- Primary myelofibrosis

- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

1.2 Disease is intermediate or high risk

AND

1.3 Patient has anemia

Product Name: Ojjaara	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

2 . Revision History

Date	Notes
12/6/2023	New guideline

Olumiant

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124907
Guideline Name	Olumiant
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Olumiant 1mg and 2mg	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine)

AND

4 - ONE of the following:

4.1 All of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Orencia (abatacept)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Olumiant therapy

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**	
Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor. **Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral co rticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant 1mg and 2 mg	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Olumiant therapy **AND** **2** - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**	
Notes	**Olumiant may be used with concomitant methotrexate, topical or inh aled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of COVID-19	

AND **2** - Patient is hospitalized* **AND** **3** - Patient requires one of the following: • Supplemental oxygen • Non-invasive mechanical ventilation • Invasive mechanical ventilation • Extracorporeal membrane oxygenation (ECMO)

Notes	*Olumiant is only FDA approved when used for COVID 19 patients in an inpatient setting

2 . Revision History

Date	Notes
5/2/2023	Updated Rheumatoid Arthritis section to remove 4mg strength per FFS clarification

Onureg

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-79897
Guideline Name	Onureg
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2021

1 . Criteria

Product Name: Onureg	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Acute Myeloid Leukemia

AND

2 - Achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy

AND

3 - Patient is not able to complete intensive curative therapy (e.g., transplant-ineligible)

Product Name: Onureg	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Onureg therapy

Product Name: Onureg	
Diagnosis	NCCN Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The use of Onureg is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Onureg	
Diagnosis	NCCN Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - There is documentation of positive clinical response to Onureg therapy	

2 . Revision History

Date	Notes
1/21/2021	Copy of NY gl-79800 New Implementations

Ophthalmic Antihistamine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116836
Guideline Name	Ophthalmic Antihistamine
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: azelastine ophth soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

Product Name: olopatadine ophth soln (Rx formulation)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

AND

2 - ONE of the following:

2.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Azelastine ophthalmic solution
- Ketotifen
- Cromolyn

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Azelastine ophthalmic solution
- Ketotifen

- Cromolyn

Opzelura

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116125
Guideline Name	Opzelura
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - One of the following:

- Greater than or equal to 3% body surface area (BSA) involvement
- Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin)

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply of non-pharmacologic topical therapies (e.g., moisturizers)

AND

6 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least TWO of the following:

- Medium or higher potency topical corticosteroid
- Elidel (pimecrolimus) cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

7 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

8 - Opzelura will only be used for short-term and/or non-continuous chronic treatment

Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in pruritus severity from baseline
- Improvement in quality of life from baseline

AND

2 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

3 - Opzelura will only be used for short-term and/or non-continuous chronic treatment

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1

	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
10/27/2022	Removed nonsegmental vitiligo auto denial criteria

Oral Oncology Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137404
Guideline Name	Oral Oncology Agents
Formulary	• Medicaid - Community & State Arizona • Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Alecensa, Alunbrig, Ayvakit, Balversa, Bosulif, Braftovi, Brukinsa, Cabometyx, Calquence, Caprelsa, Cometriq, Copiktra, Cotellic, Daurismo, Erivedge, Erleada, etoposide capsules, Gavreto, Gilotrif, Hycamtin capsules, Ibrance, Iclusig, Idhifa, Imbruvica, Inlyta, Inrebic, Brand Iressa, generic gefitinib, Jakafi, Jaypirca, Kisqali, Kisqali-Femara Co-pack, Koselugo, Krazati, Lenvima, Lonsurf, Lorbrena, Lumakras, Lynparza, Lytgobi, Mekinist, Mektovi, Nerlynx, Brand Nexavar, generic sorafenib, Ninlaro, Nubeqa, Odomzo, Orserdu, Pemazyre, Piqray, Pomalyst, Qinlock, Retevmo, Rezlidhia, Rozlytrek, Rubraca, Rydapt, Stivarga, Sprycel, Tabrecta, Tabloid, Tafinlar, Tagrisso, Talzenna, Brand Tarceva, generic erlotinib, Tasigna, Tazverik, Tepmetko, Tibsovo, Tukysa, Turalio, Brand Tykerb, generic lapatinib, Vanflyta, Venclexta, Verzenio, Vitrakvi, Vizimpro, Votrient, Xalkori, Brand Xeloda, generic capecitabine, Xospata, Xpovio, Xtandi, Yonsa, Zejula, Zelboraf, Zolinza, Zydelig, Zykadia, Brand Zytiga, generic abiraterone, Akeega, Brand Temodar capsules, generic temozolomide capsules	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
12/6/2023	Added new Rozlytrek GPI.

Orencia (abatacept)

Prior Authorization Guideline

Guideline ID	GL-137450
Guideline Name	Orencia (abatacept)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Orencia Clickject, Orencia prefilled syringe	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to ONE nonbiologic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]

Product Name: Orencia Clickject, Orencia prefilled syringe	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Orencia Clickject, Orencia prefilled syringe	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs):

- leflunomide (Arava)
- methotrexate (Rheumatrex/Trexall)

Product Name: Orencia Clickject, Orencia prefilled syringe	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Orencia Clickject, Orencia prefilled syringe	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - Patient is 2 years of age or older

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Orencia Clickject, Orencia prefilled syringe	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
12/7/2023	Added age criterion to PsA indication.

Orfadin (nitisinone)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129564
Guideline Name	Orfadin (nitisinone)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Brand Orfadin, generic nitisinone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary tyrosinemia type 1	

2 . Revision History

Date	Notes

8/8/2023	Updated guideline name and GPIs

Orgovyx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-81521
Guideline Name	Orgovyx
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Orgovyx	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced prostate cancer

AND

2 - Patient is a candidate for at least one year of continuous androgen-deprivation therapy

AND

3 - ONE of the following:

- Evidence of biochemical [PSA (prostate-specific antigen)] or clinical relapse after local primary intervention with curative intent
- Newly diagnosed hormone-sensitive metastatic disease
- Advanced localized disease unlikely to be cured by local primary intervention with curative intent

AND

4 - Patient has been without any major adverse cardiovascular events within 6 months before initiation (e.g., myocardial infarction, stroke)

Product Name: Orgovyx	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Orgovyx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Orgovyx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orgovyx therapy

2 . Revision History

Date	Notes
3/1/2021	New guideline

Orilissa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110766
Guideline Name	Orilissa
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Orilissa 150 mg	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

4 - History of trial and failure, contraindication, or intolerance after a three month trial to ONE of the following:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Product Name: Orilissa 150 mg	
Approval Length	6 months*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months**

Notes	*NOTE: Authorization for Orilissa 150 mg will be issued for 6 months up to a maximum of 24 months. **NOTE: Orilissa 150 mg once daily is indicated for a maximum of 24 months.

Product Name: Orilissa 200 mg	
Approval Length	6 months*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

4 - History of trial and failure, contraindication, or intolerance after a three month trial to ONE of the following:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND **5** - Prescribed by or in consultation with ONE of the following: • Obstetrics/Gynecologist (OB/GYN) • Reproductive endocrinologist	
Notes	*NOTE: Orilissa 200 mg twice daily is indicated for a maximum of 6 months.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Orkambi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116664
Guideline Name	Orkambi
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Orkambi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

AND

3 - The patient is 1 year of age or older

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Orkambi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Orkambi therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Revision History

Date	Notes
11/7/2022	Updated age requirement, added new GPI

Osphena

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-63859
Guideline Name	Osphena
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Osphena	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause*

AND

2 - History of failure, contraindication, or intolerance to BOTH of the following: • Estradiol vaginal cream • Estradiol vaginal tablet	
Notes	*Treatment of dyspareunia is a benefit exclusion.

Product Name: Osphena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
3/16/2020	New program

Otezla

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110684
Guideline Name	Otezla
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Behcet's Disease

AND

2 - Patient has active oral ulcers

AND

3 - History of failure, contraindication, or intolerance to one non-biologic (e.g., corticosteroids, colchicine) within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis, Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

AND

2 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Otezla	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

AND

2 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Oxbryta (voxelotor)

Prior Authorization Guideline

Guideline ID	GL-121017
Guideline Name	Oxbryta (voxelotor)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Oxbryta	
Diagnosis	Sickle Cell Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Patient is 4 years of age or older

AND

3 - One of the following:

3.1 Patient is currently receiving hydroxyurea therapy

OR

3.2 Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy

AND

4 - Patient has previously experienced 1 or more sickle cell-related vaso-occlusive crises within the previous 12 months

AND

5 - Baseline hemoglobin (Hb) less than or equal to 10.5 grams per deciliter

AND

6 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

7 - Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

8 - Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease

Product Name: Oxbryta	
Diagnosis	Sickle Cell Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least one of the following:

1.1 Increase in hemoglobin (Hb) by greater than or equal to 1 gram per deciliter from baseline

OR

1.2 Decrease in indirect bilirubin from baseline

OR

1.3 Decrease in percent reticulocyte count from baseline

OR

1.4 Patient has experienced a reduction in sickle cell-related vaso-occlusive crises

AND

2 - Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

3 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND **4** - Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

2 . Revision History

Date	Notes
2/8/2023	Added new 300 mg strength to GPI list, cleaned up criteria.

Oxervate

Prior Authorization Guideline

Guideline ID	GL-64512
Guideline Name	Oxervate
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Oxervate	
Diagnosis	Neurotrophic keratitis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Stage 2 or 3 neurotrophic keratitis

AND

2 - History of failure to at least one OTC ocular artificial tear product (e.g., Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe® XP)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Oxlumo (lumasiran)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118271
Guideline Name	Oxlumo (lumasiran)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Oxlumo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2 - Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by BOTH of the following:

2.1 ONE of the following:

- Elevated urinary oxalate excretion
- Elevated plasma oxalate concentration
- Spot urinary oxalate to creatinine molar ratio greater than normal for age

AND

2.2 ONE of the following:

- Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
- Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity

AND

3 - Patient has not received a liver transplant

AND

4 - Prescribed by or in consultation with ONE of the following:

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

Product Name: Oxlumo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration)

AND

2 - Patient has not received a liver transplant

AND

3 - Prescribed by or in consultation with ONE of the following:

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

2 . Revision History

Date	Notes
12/12/2022	Updated guideline name and all criteria to match FFS.

Palforzia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-95255
Guideline Name	Palforzia
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2021

1 . Criteria

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by BOTH of the following:

1.1 A serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L (kilo units of allergen per liter)

AND

1.2 A mean wheal diameter that is at least 3mm (millimeters) larger than the negative control on skin-prick testing for peanut

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is 4 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

OR

2.2 BOTH of the following:

- Patient is 4 years of age and older
- Patient is in the up-dosing or maintenance phase of therapy

AND

3 - Used in conjunction with a peanut-avoidant diet

AND

4 - Patient does not have one of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months
- Severe or poorly controlled asthma

AND

5 - Prescribed by or in consultation with an allergist or immunologist

AND

6 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Palforzia therapy

AND

2 - Used in conjunction with a peanut-avoidant diet

AND

3 - Prescribed by or in consultation with an allergist or immunologist

AND

4 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

2 . Revision History

Date	Notes

9/30/2021	Corrected “meal” to “mean” typo at step 1.2 of initial auth.

Palynziq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110621
Guideline Name	Palynziq
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient is actively on a phenylalanine-restricted diet

AND

3 - Physician attestation that the patient will not be receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride)

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromoles per liter

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is actively on a phenylalanine-restricted diet

AND

2 - ONE of the following:

2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromoles per liter

OR

2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

OR

2.3 BOTH of the following:

2.3.1 Patient is in initial titration/maintenance phase of dosing regimen (week 1-33)

AND

2.3.2 Patient will receive maximum labeled dosage of 40 milligrams (mg) once daily if response has not been obtained after 24 weeks of 20 mg once daily maintenance dosing

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride) [Prescription claim history that does not show any concomitant Kuvan claim within 60 days of reauthorization request may be used as documentation]

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Panretin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110325
Guideline Name	Panretin
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Panretin	
Diagnosis	AIDS-related Kaposi's Sarcoma (KS)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired immunodeficiency syndrome (AIDS)-related Kaposi's Sarcoma (KS)

AND

2 - Patient is not receiving systemic anti-KS treatment

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Panretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Panretin therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Pediculicides

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110859
Guideline Name	Pediculicides
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Natroba, generic spinosad, Sklice	
Diagnosis	Head lice
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of topical treatment of head lice infestations

AND

2 - For Brand Natroba requests ONLY: Trial and failure to generic spinosad suspension (verified via paid pharmacy claims or submission of medical records/chart notes)

2 . Revision History

Date	Notes
8/10/2022	C&S to match AZM 10.1.22

Phexxi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129328
Guideline Name	Phexxi
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Phexxi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for the prevention of pregnancy

AND

2 - ONE of the following:

2.1 Failure to ALL of the following other methods of contraception as confirmed by claims history or submission of medical records:

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

OR

2.2 History of intolerance or contraindication to ALL of the following methods of contraception (please document intolerance or contraindication):

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

AND

3 - ONE of the following:

3.1 Failure to nonoxynol-9 based spermicide as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to nonoxynol-9 based spermicide (please document intolerance or contraindication)

AND

4 - Provider attests they have counseled the patient regarding higher rate of pregnancy

prevention with the use of other methods of contraception (e.g., injection, oral contraception, transdermal patch, vaginal ring) compared to Phexxi

Pradaxa Pellet Packs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134163
Guideline Name	Pradaxa Pellet Packs
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Pradaxa Pellet Packs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 8 years of age or younger

OR

2 - ALL of the following:

2.1 Patient is between 9 and 12 years of age

AND

2.2 Requested medication is being used for ONE of the following diagnoses:

- Treatment of venous thromboembolic events (VTE) in patients who have been treated with a parenteral anticoagulant for at least 5 days
- To reduce the risk of recurrence of VTE in patients who have been previously treated

AND

2.3 ONE of the following:

- Trial and failure, contraindication, or intolerance to Brand Pradaxa capsules (verified via paid pharmacy claims or submitted chart notes)
- Patient is unable to swallow oral tablets/capsules

2 . Revision History

Date	Notes
10/3/2023	New

Praluent

Prior Authorization Guideline

Guideline ID	GL-132850
Guideline Name	Praluent
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following:	

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following*:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment low density lipoprotein cholesterol (LDL-C) of ONE of the following:

- Greater than 190 milligrams per deciliter (mg/dL)
- Greater than 155 mg/dL if less than 16 years of age

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C of ONE of the following:

- Greater than 190 mg/dL
- Greater than 155 mg/dL if less than 16 years of age

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low density lipoprotein), apoB (apolipoprotein B), or PCSK9 (proprotein convertase subtilisin/kexin type 9) gene*
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy [i.e. atorvastatin 40-80 milligrams (mg), rosuvastatin 20-40mg] and will continue to receive high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without creatine kinase [CK] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin

XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Used as an adjunct to a low-fat diet and exercise

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist

- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Notes	*Note: Results of prior genetic testing can be submitted as confirmatio n of diagnosis of HeFH.

Product Name: Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Product Name: Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 500 mg/dL (milligrams per deciliter)
- Treated LDL-C greater than 300 mg/dL

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL [low-density lipoprotein] apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

2 . Revision History

Date	Notes
9/11/2023	Updated SP to standard formulary. Update to account for 2022 ACC recommendations of a lower LDL threshold of 55mg/dl for patients wi th ASCVD at very high risk.

Preferred Drugs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110767
Guideline Name	Preferred Drugs
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Diagnosis	Prior Authorization Administrative Guideline for Preferred Drugs Without Drug-Specific Criteria
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

1.3 If the patient is less than FDA minimum age, the prescriber attests they are aware of FDA labeling and feels the treatment with the requested product is medically necessary. (Document rationale for use)

Notes	Medications used solely for anti-obesity/weight loss, cosmetic (e.g., al opecia, actinic keratosis, vitiligo), erectile dysfunction, and sexual dysf unction purposes are NOT medically accepted indications and are NO T recognized as a covered benefit. Erectile dysfunction drugs (Cialis/T adalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Preferred Non-Solid Dosage Forms

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-122059
Guideline Name	Preferred Non-Solid Dosage Forms
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	4/16/2023

1 . Criteria

Diagnosis	Requests for Non-Solid Dosage Forms
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 Requested drug must be used for an FDA (Food and Drug Administration)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 The patient is able to swallow a solid dosage form

AND

3.1.2 ONE of the following:

3.1.2.1 History of failure, contraindication, or intolerance to at least THREE preferred* solid oral dosage forms (Prior trials of formulary/PDL (preferred drug list) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products.)

OR

3.1.2.2 There are no preferred formulary alternatives for the requested drug

OR

3.2 Patient is unable to swallow a solid dosage form **OR** **3.3** Patient utilizes a feeding tube for medication administration **OR** **3.4** Request is for a nebulized formulation of an inhaled medication for a patient who has an inability to effectively utilize an agent in an inhaler formulation due to neuromuscular or cognitive disability, or other evidence of lack of response to the inhaled formulation supported by clinical documentation	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Pretomanid

Prior Authorization Guideline

Guideline ID	GL-66196
Guideline Name	Pretomanid
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	7/1/2020

1 . Criteria

Product Name: Pretomanid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary extensively drug resistant (XDR) tuberculosis (TB)

OR

1.2 Treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB) **AND** **2** - Pretomanid will be used in combination with bedaquiline and linezolid

2 . Revision History

Date	Notes
5/12/2020	New program

Prevymis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127778
Guideline Name	Prevymis
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Prevymis	
Diagnosis	CMV Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT) Recipients
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is a recipient of an allogeneic hematopoietic stem cell transplant

AND

2 - Patient is cytomegalovirus (CMV) seropositive (R+)

AND

3 - Provider attests that Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

Product Name: Prevymis	
Diagnosis	CMV Prophylaxis in Kidney Transplant Recipients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is a recipient of a kidney transplant

AND

2 - Patient is cytomegalovirus (CMV) seronegative [Donor CMV seropositive/Recipient CMV seronegative (D+/R-)]

AND

3 - Provider attests that Prevymis will be initiated between Day 0 and Day 7 post-transplantation; and is being prescribed as prophylaxis and not treatment of CMV infection

2 . Revision History

Date	Notes
7/10/2023	Updated indications and added new criteria section for kidney transplant, cleaned up criteria.

Procysbi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110875
Guideline Name	Procysbi
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nephropathic cystinosis

AND

2 - Patient is 1 year of age or older

AND **3** - History of failure or intolerance to Cystagon (immediate-release cysteamine bitartrate)*

Notes	*Frequency of dosing and/or lack of compliance to dosing regimens is not generally considered an indication of medical necessity.

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Procysbi therapy

2 . Revision History

Date	Notes
8/10/2022	C&S to match AZM 10.1.22

Progesterone - Non-Oral

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64399
Guideline Name	Progesterone - Non-Oral
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Crinone, Endometrin	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Treatment is for non-infertility use (e.g., secondary amenorrhea, reduce the risk of recurrent spontaneous preterm birth)	

2 . Revision History

Date	Notes

3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Progesterone- Oral

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-88853
Guideline Name	Progesterone- Oral
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	8/1/2021

1 . Criteria

Product Name: Brand Prometrium, generic progesterone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Amenorrhea
- Endometrial hyperplasia or prevention of endometrial hyperplasia
- Abnormal uterine or vaginal bleeding
- History of preterm birth
- Prevention of preterm delivery for current pregnancy

2 . Revision History

Date	Notes
6/24/2021	Copy of NY GL-88451. Removed inactive GPI and updated new GPI for Prometrium

Provigil, Nuvigil

Prior Authorization Guideline

Guideline ID	GL-110317
Guideline Name	Provigil, Nuvigil
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Narcolepsy, Obstructive Sleep Apnea, Shift Work Disorder, Idiopathic Hypersomnia (off label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Narcolepsy
- Excessive sleepiness due to obstructive sleep apnea
- Excessive sleepiness due to shift work disorder (circadian rhythm sleep disorder, shift work type)

- Idiopathic hypersomnia

AND

2 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Fatigue due to Multiple Sclerosis (off-label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient is experiencing fatigue

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment-resistant depression, defined as BOTH of the following:

1.1 Diagnosis of ONE of the following:

- Major depressive disorder (MDD)
- Bipolar depression

AND

1.2 History of failure, contraindication, or intolerance to at least TWO antidepressants from different classes (e.g., SSRIs [selective serotonin reuptake inhibitors], SNRIs [serotonin-norepinephine reuptake inhibitors], bupropion)

AND

2 - Used as adjunctive therapy

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND **2** - Used as adjunctive therapy **AND** **3** - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Pulmonary Arterial Hypertension (PAH) Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127863
Guideline Name	Pulmonary Arterial Hypertension (PAH) Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Brand Adcirca, generic ambrisentan, generic bosentan, generic sildenafil 20 mg tabs, generic sildenafil susp, Brand Revatio susp, Adempas, generic Alyq, generic tadalafil 20 mg (PAH), Brand Letairis, Liqrev, Opsumit, Orenitram Titration, Orenitram, Brand Revatio tabs, Tadliq, Brand Tracleer, Tracleer oral susp, Tyvaso, Tyvaso DPI, Uptravi Titration, Uptravi tabs, Ventavis	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pulmonary arterial hypertension	

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - ONE of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with ONE of the following:

- Pulmonologist
- Cardiologist

AND

5 - If the request is non-preferred*, patient has a history of failure, contraindication, or intolerance to at least THREE preferred* alternatives (NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

AND

6 - If the request is for generic tadalafil 20 mg (PAH) or Alyq, patient must have tried and failed brand Adcirca

AND

7 - If the request is for Brand Revatio suspension or generic sildenafil suspension, BOTH of the following:

- Patient is between 12 and 17 years of age
- Trial and failure or intolerance to oral tablet formulation

AND

8 - If the request is for Liqrev, ALL of the following:

- Trial and failure or intolerance to oral tablet formulation
- History of failure to generic sildenafil suspension
- History of failure to Revatio suspension

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand Adcirca, generic ambrisentan, generic bosentan, generic sildenafil 20 mg tabs, generic sildenafil susp, Brand Revatio susp, Adempas, generic Alyq, generic tadalafil 20 mg (PAH), Brand Letairis, Liqrev, Opsumit, Orenitram Titration, Orenitram, Brand Revatio tabs, Tadliq, Brand Tracleer, Tracleer oral susp, Tyvaso, Tyvaso DPI, Uptravi Titration, Uptravi tabs, Ventavis	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Adempas	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

2 - Prescribed by or in consultation with ONE of the following:

- Pulmonologist
- Cardiologist

Product Name: Adempas	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
7/11/2023	Added liqrev and drug specific criteria

Pulmozyme

Prior Authorization Guideline

Guideline ID	GL-82276
Guideline Name	Pulmozyme
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Pulmozyme	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Cystic Fibrosis	

2 . Revision History

Date	Notes
3/8/2021	Added product name list.

Pyrukynd (mitapivat)

Prior Authorization Guideline

Guideline ID	GL-110600
Guideline Name	Pyrukynd (mitapivat)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count)

AND

1.2 Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene:

- Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant
- Patients is not homozygous for the c.1436G>A (p.R479H) variant
- Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

1.3 Hemoglobin is less than or equal to 10g/dL

AND

1.4 Patient has symptomatic anemia or is transfusion dependent

AND

1.5 Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs)

AND

2 - Prescribed by or in consultation with a hematologist

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy [e.g., hemoglobin greater than or equal to 1.5g/dL from baseline, reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the fixed dose period compared with the patient's historical transfusion burden, improvement in markers of hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)] **AND** **2** - Prescribed by or in consultation with a hematologist

Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 1-month authorization should be issued one time for Pyrukynd gradual therapy discontinuation.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Qbrexza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125825
Guideline Name	Qbrexza
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Qbrexza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary axillary hyperhidrosis

AND

2 - ONE of the following:

2.1 Failure to Xerac-AC as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to Xerac-AC (please specify contraindication or intolerance)

2 . Revision History

Date	Notes
5/16/2023	New

Qutenza (capsaicin)

Prior Authorization Guideline

Guideline ID	GL-129656
Guideline Name	Qutenza (capsaicin)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Qutenza	
Diagnosis	Neuropathic pain associated with postherpetic neuralgia (PHN)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of neuropathic pain associated with postherpetic neuralgia (PHN)

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial and failure, contraindication, or intolerance to ALL of the following:

- gabapentin
- pregabalin
- minimum 60-day trial of a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, desipramine)
- generic lidocaine 5% patch
- topical capsaicin cream

Product Name: Qutenza	
Diagnosis	Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial and failure, contraindication, or intolerance to ALL of the following:

- gabapentin
- pregabalin
- minimum 60-day trial of a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, desipramine)
- generic lidocaine 5% patch
- topical capsaicin cream
- duloxetine

Product Name: Qutenza	
Diagnosis	Neuropathic pain associated with PHN, Neuropathic pain associated with DPN of the feet
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - It has been at least 3 months since the last application/administration

AND

2 - Patient experienced pain relief with a prior course of therapy

AND

3 - Patient is experiencing a return of neuropathic pain

2 . Revision History

Date	Notes
8/9/2023	New guideline

Radicava (edaravone)

Prior Authorization Guideline

Guideline ID	GL-116003
Guideline Name	Radicava (edaravone)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) per the revised EL Escorial and Airlie House diagnostic criteria

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

AND

3 - Patient has scores greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment

AND

4 - Patient has a percent forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

Product Name: Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to therapy (e.g., slowing in the decline of functional abilities)

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

2 . Revision History

Date	Notes
10/21/2022	Removed the Radicava-solution (Medical benefit)

Ranolazine products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116054
Guideline Name	Ranolazine products
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Brand Ranexa, generic ranolazine	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of ONE of the following standard anti-angina treatments:

1.1 One beta-blocker [e.g. Lopressor (metoprolol), Inderal (propranolol)]

OR

1.2 One calcium channel blocker [e.g. Procardia XL (nifedipine ER), Cardizem LA/Cardizem CD (diltiazemER)]

OR

1.3 One long acting nitrate therapy [e.g. Imdur (isosorbide mononitrate), Isordil (isosorbide dinitrate), Nitro-Time/Nitro-Dur/Nitro-Bid (nitroglycerin ER)]

AND

2 - For Brand Ranexa requests ONLY: Trial and failure to generic ranolazine (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Aspruzyo Sprinkle	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of ONE of the following standard anti-angina treatments:

1.1 One beta-blocker [e.g. Lopressor (metoprolol), Inderal (propranolol)]

OR

1.2 One calcium channel blocker [e.g. Procardia XL (nifedipine ER), Cardizem LA/Cardizem CD (diltiazemER)]

OR

1.3 One long acting nitrate therapy [e.g. Imdur (isosorbide mononitrate), Isordil (isosorbide dinitrate), Nitro-Time/Nitro-Dur/Nitro-Bid (nitroglycerin ER)]

AND

2 - One of the following:

2.1 Trial and failure to generic ranolazine (verified via paid pharmacy claims or submission of medical records/chart notes)

OR

2.2 One of the following:

- Patient is 8 years of age or younger
- Patient is unable to swallow the oral tablet (solid formulation) due to swallowing difficulties

2 . Revision History

Date	Notes
10/26/2022	Added Aspruzyo Sprinkle as target. Updated guideline name to Rano lazine Products

Rayos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110335
Guideline Name	Rayos
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Rayos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) or claims history documenting an intolerance to generic prednisone tablets which is unable to be resolved with attempts to minimize the adverse effects where appropriate

AND

4 - History of failure, contraindication, or intolerance to TWO the following:

- Dexamethasone tablet, oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet
- Prednisolone tablet, oral solution

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes

8/4/2022	C&S to match AZM as of 10.1.22

Recorlev (levoketoconazole)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110579
Guideline Name	Recorlev (levoketoconazole)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Recorlev	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Cushing's disease

AND

1.2 ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name: Recorlev	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy

Product Name: Recorlev	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recorlev will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Recorlev	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Rectiv

Prior Authorization Guideline

Guideline ID	GL-64404
Guideline Name	Rectiv
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Rectiv	
Diagnosis	Pain Associated with Chronic Anal Fissures
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with chronic anal fissures

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Regranex

Prior Authorization Guideline

Guideline ID	GL-110285
Guideline Name	Regranex
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Regranex	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a lower extremity diabetic neuropathic ulcer	

2 . Revision History

Date	Notes

8/4/2022	C&S to match AZM as of 10.1.22

Relyvrio (sodium phenylbutyrate and taurursodiol)

Prior Authorization Guideline

Guideline ID	GL-121092
Guideline Name	Relyvrio (sodium phenylbutyrate and taurursodiol)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Diagnosis of ALS is further supported by neurogenic changes in electromyography (EMG)

AND

3 - Patient has had ALS symptoms for less than or equal to 18 months

AND

4 - Patient has a percent (%) forced vital capacity (FVC) or slow vital capacity (SVC) greater than or equal to 60% at the start of treatment

AND

5 - Patient does not require permanent noninvasive ventilation or invasive ventilation

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

Product Name: Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting slowed disease progression from baseline

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

2 . Revision History

Date	Notes
2/8/2023	New guideline

Repatha

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132857
Guideline Name	Repatha
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Repatha	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH), Atherosclerotic cardiovascular disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following*:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 190 milligrams per deciliter (mg/dL) (greater than 155 mg/dL if less than 16 years of age)

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first degree relative less than 60 years of age
- Family history of myocardial infarction in second degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first or second degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first or second degree relative
- Family history of tendinous xanthomata and or arcus cornealis in first or second degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age)

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low-density lipoprotein), apoB (Apolipoprotein B), or PCSK9 (Proprotein convertase subtilisin/kexin type 9) gene*
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes

- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive high-intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin [i.e.

simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate, and high intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate, and high intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Used as an adjunct to a low-fat diet and exercise

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HeFH .

Product Name: Repatha

Diagnosis	Heterozygous familial hypercholesterolemia (HeFH), Atherosclerotic cardiovascular disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Product Name: Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 500 mg/dL (milligrams per deciliter)
- Treated LDL-C greater than 300 mg/dL

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL [low-density lipoprotein] apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist

- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is continuing a low-fat diet and exercise regimen

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist

• Lipid Specialist **AND** **5** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

2 . Revision History

Date	Notes
9/11/2023	Updated SP to standard formulary. Update to account for 2022 ACC recommendations of a lower LDL threshold of 55mg/dl for patients wi th ASCVD at very high risk.

Restasis (cyclosporine)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118268
Guideline Name	Restasis (cyclosporine)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Restasis Multidose, Brand Restasis, generic cyclosporine (ophth) 0.05%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- FDA approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type, and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential patient outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia - Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

2 . Revision History

Date	Notes
12/12/2022	New guideline

Revcovi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-69022
Guideline Name	Revcovi
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/14/2020

1 . Criteria

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe combined immunodeficiency disease (SCID)

AND

2 - Deficiency of adenosine deaminase is confirmed by one of the following:

- Deficiency or absence of adenosine deaminase (ADA) in plasma, lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villus
- Increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates compared to laboratory standard
- Decrease in ATP (Adenosine triphosphate) concentration in erythrocytes
- Molecular genetic confirmation of mutations in both alleles of the ADA1 gene
- Positive screening by T cell receptor excision circles (TRECs)

AND

3 - One of the following:

- Patient is not a suitable candidate for hematopoietic cell transplantation (HCT)
- Patient has failed HCT
- Patient is awaiting HCT

AND

4 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received treatment with Revcovi (elapegademase) therapy

AND

2 - Patient has experienced a positive clinical response to therapy (e.g., normalization of plasma ADA activity, erythrocyte dATP levels, improvement of disease symptoms, etc.)

AND **3** - Dosing is in accordance with the United States Food and Drug Administration approved labeling

2 . Revision History

Date	Notes
7/14/2020	2020 Implementation

Revlimid (lenalidomide)

Prior Authorization Guideline

Guideline ID	GL-110594
Guideline Name	Revlimid (lenalidomide)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: generic lenalidomide	
Diagnosis	All indications, Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Trial and failure to Brand Revlimid (verified via paid pharmacy claims or submission of medical records)	

Product Name: Brand Revlimid	
Diagnosis	Multiple Myeloma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of multiple myeloma

Product Name: Brand Revlimid	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

2.1 Patient has a diagnosis of anemia due to myelodysplastic syndrome WITHOUT deletion 5q

AND

2.2 ONE of the following:

2.2.1 Serum erythropoetin levels greater than 500 mU (milliunits)/mL (milliliter)

OR

2.2.2 ALL of the following:

2.2.2.1 Serum erythropoetin levels less than or equal to 500 mU/mL

AND

2.2.2.2 Ring sideroblasts less than 15%

AND

2.2.2.3 ONE of the following:

- Revlimid therapy is in combination with an erythropoietin [e.g., Epogen, Procrit, Retacrit (epoetin alfa)]
- History of failure, contraindication, or intolerance to erythropoietins [e.g., Epogen, Procrit, Retacrit (epoetin alfa)]

OR

2.2.3 ALL of the following:

2.2.3.1 Serum erythropoetin levels less than or equal to 500 mU/mL

AND

2.2.3.2 Ring sideroblasts greater than or equal to 15%

AND

2.2.3.3 No response to an erythropoietin in combination with a granulocyte-colony stimulating factor (G-CSF)

OR

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

3.1 Diagnosis of myelodysplastic/myeloproliferative neoplasms (MDS/MPN) overlap neoplasm

AND

3.2 Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Product Name: Brand Revlimid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following diagnoses:

- Mantle cell lymphoma (MCL)
- Diffuse large B-cell lymphoma (patients 60 to 80 years old)
- Follicular lymphoma
- Gastric mucosa-associated lymphoid tissue (MALT) lymphoma
- Nodal marginal zone lymphoma
- Non-gastric MALT lymphoma
- Splenic marginal zone lymphoma

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

2.1 ONE of the following diagnoses:

- Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
- Castleman's Disease (CD)
- Diffuse large B-cell lymphoma (patients who are less than 60 years old)
- High-grade B-cell lymphoma
- Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorders

AND

2.2 NOT used as first line therapy

Product Name: Brand Revlimid	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of Hodgkin lymphoma

AND

2 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

3 - Used as third-line or subsequent therapy

Product Name: Brand Revlimid	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of systemic light chain amyloidosis

AND

2 - ONE of the following:

2.1 Used in combination with dexamethasone

OR

2.2 Used in combination with dexamethasone and cyclophosphamide

Product Name: Brand Revlimid	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

AND

2 - ONE of the following:

- Used post first-line chemoimmunotherapy maintenance therapy
- Used post second-line maintenance therapy
- Used for relapsed or refractory disease

Product Name: Brand Revlimid	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of ONE of the following:

- Mycosis Fungoides (MF) / Sezary Syndrome (SS)
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders

Product Name: Brand Revlimid	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has ONE of the following diagnoses:

- Peripheral T-cell lymphoma
- T-cell leukemia/lymphoma

- Hepatosplenic gamma-delta T-cell lymphoma

AND

2 - NOT used as first line therapy

Product Name: Brand Revlimid	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of primary central nervous system lymphoma

Product Name: Brand Revlimid	
Diagnosis	AIDS–Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has diagnosis of AIDS-related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - NOT used as first line therapy

Product Name: Brand Revlimid	
Diagnosis	*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient does not show evidence of progressive disease while on Revlimid therapy

Notes	*Multiple Myeloma, Myelodysplastic Syndromes (MDS), B-Cell Lymphomas, Hodgkin Lymphoma, Systemic Light Chain Amyloidosis, Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Primary Cutaneous Lymphomas, T-Cell Lymphomas, Primary CNS Lymphomas, AIDS-Related Kaposi Sarcoma

Product Name: Brand Revlimid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of myelofibrosis

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 BOTH of the following:

2.1.1 Serum erythropoietin levels less than 500 mU (milliunits)/mL (milliliter)

AND

2.1.2 History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]

OR

2.2 Serum erythropoietin levels greater than or equal to 500 mU/mL

Product Name: Brand Revlimid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting the patient has evidence of symptom improvement or reduction in spleen/liver volume while on Revlimid

Product Name: Brand Revlimid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Revlimid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Revlimid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Revlimid therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Reyvow

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110350
Guideline Name	Reyvow
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Reyvow	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe migraine headaches with or without aura

AND

2 - Used for acute treatment of migraine

AND

3 - Patient is 18 years of age or older

AND

4 - Documentation of a one month trial resulting in therapeutic failure, contraindication, or intolerance to THREE ofthe following:

- naratriptan tablets
- rizatriptan tablets/ODT (oral disintegrating tablets)
- sumatriptan tablets/auto injection/cartridge or Imitrex nasal spray (Brand only)
- zolmitriptan tablets/ODT

AND

5 - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine:

- Neurologist
- Pain Specialist
- Headache Specialist*

AND

6 - Prescriber attests to ALL of the following:

- Patient has been informed the use of Reyvow may result in significant CNS impairment, and may impact the patient's ability to drive or operate machinery for 8 hours after each dose
- If used concurrently with a benzodiazepine or other drugs that could potentially cause central nervous system (CNS) depression, the prescriber has acknowledged that they have completed an assessment of increased risk for sedation and other cognitive and/or neuropsychiatric adverse events
- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

AND

7 - Both of the following:

7.1 One of the following

7.1.1 The patient must have a history of therapeutic failure, contraindication, or intolerance to THREE of the following:

- Amitriptyline (Elavil)**
- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)**
- Divalproex sodium [Depakote/Depakote ER (extended-release)]**
- Topiramate (Topamax)**
- VENLAFAXINE [EFFEXOR/EFFEXOR XR (EXTENDED-RELEASE)]**

OR

7.1.2 The patient must be currently treated with one of the following prophylactic therapies unless there is a contraindication or intolerance to ALL:

- Amitriptyline (Elavil)**
- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)**
- Divalproex sodium [Depakote/Depakote ER (extended-release)]**
- Topiramate (Topamax)**
- Venlafaxine [Effexor/Effexor XR (extended-release)]**

AND

7.2 Both of the Following

7.2.1 History of a therapeutic failure after 3 month trial, contraindication, or intolerance to two of the following biologic calcitonin gene-related peptide receptor (CGRP) antagonists for preventive treatment of migraine

- Ajovy (fremanezumab)
- Emgality (galcanezumab)
- Aimovig (erenumab)

AND

7.2.2 History of a therapeutic failure, contraindication, or intolerance to Ubrelvy

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS) **Drugs may require PA

Product Name: Reyvow	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine:

- Neurologist
- Pain Specialist
- Headache Specialist*

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Rezurock (belumosudil)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110584
Guideline Name	Rezurock (belumosudil)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease - Twice daily (BID) Therapy
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Patient is using medication concomitantly with one of the following:

- Strong CYP3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifampin)
- Proton pump inhibitor (e.g., omeprazole, pantoprazole, lansoprazole)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Rhofade

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110318
Guideline Name	Rhofade
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Rhofade	
Diagnosis	Persistent erythema associated with rosacea
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of persistent erythema associated with rosacea

AND

2 - ONE of the following:

2.1 History of a 30 day or longer trial and failure of one of the following:

- metronidazole cream, gel, or lotion
- azelaic acid gel

OR

2.2 Contraindication or intolerance to both of the following:

- metronidazole cream, gel, or lotion
- azelaic acid gel

Product Name: Rhofade	
Diagnosis	Persistent erythema associated with rosacea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Rhofade therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Rinvoq (upadacitinib)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-133001
Guideline Name	Rinvoq (upadacitinib)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

AND

3.2 History of failure, contraindication or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Humira (adalimumab) or Enbrel (etanercept)
- infliximab
- Orencia (abatacept)
- Xeljanz oral tablet (tofacitinib)

AND

4 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) oral tablet

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

	***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation [e.g., C-reactive protein (CRP) levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 Trial and failure, contraindication, or intolerance to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Xeljanz (tofacitinib) oral tablet

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP ***Patients requesting initial authorization who were established on th

	erapy via the receipt of a manufacturer supplied sample at no cost in t he prescriber's office or any form of assistance from manufacturer spo nsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy **AND** **2** - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)* **AND** **3** - Prescribed by or in consultation with a rheumatologist	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhale d corticosteroids, and/or low stable dosages of oral corticosteroids (eq uivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - Submission of medical records documenting one of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

5.1 History of failure, contraindication, or intolerance to BOTH of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

AND

5.2 Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting trial and failure of a minimum 12-week supply of Dupixent (dupilumab) **

AND

6 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCPA ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

3 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies (document drug, date, and duration of trial):

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine

- Corticosteroids (e.g., prednisone)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Humira (adalimumab) or Enbrel (etanercept)
- infliximab
- Xeljanz oral tablet (tofacitinib)

AND

4 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroids (e.g., prednisone)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Cimzia (certolizumab)
- Humira (adalimumab)
- infliximab

AND

4 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required. PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by at least ONE of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05

High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05

	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
9/13/2023	Updated abbreviations in Crohn’s Disease section to be "CD" vs. "U C"

Ryaltris

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116311
Guideline Name	Ryaltris
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Ryaltris	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure to BOTH of the following as separate agents:

- generic mometasone nasal spray
- azelastine or olopatadine nasal spray

2 . Revision History

Date	Notes
11/7/2022	New guideline following FFS.

Samsca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-89157
Guideline Name	Samsca
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Brand Samsca, generic tolvaptan	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of clinically significant euvolemic hyponatremia
- Diagnosis of clinically significant hypervolemic hyponatremia

AND

2 - Patient has not responded to fluid restriction

AND

3 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge

Scemblix

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120211
Guideline Name	Scemblix
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Scemblix	
Diagnosis	Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myeloid leukemia (CML)	

AND

2 - Disease is Philadelphia chromosome-positive (Ph+)

AND

3 - Disease is in chronic phase

AND

4 - ONE of the following:

- Patient has been previously treated with two or more tyrosine kinase inhibitors [e.g., Bosulif (bosutinib), imatinib (Gleevec) Sprycel [dasatinib], Tasigna (nilotinib)]
- Disease is T315I mutation positive

Product Name: Scemblix	
Diagnosis	Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+CML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Scemblix therapy

Product Name: Scemblix	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Scemblix	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Scemblix therapy

2 . Revision History

Date	Notes
1/17/2023	Separated AZ into its own guideline.

Sedative Hypnotics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-112732
Guideline Name	Sedative Hypnotics
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Ambien, Brand Ambien CR, generic zolpidem ER, zolpidem SL, Edluar, Zolpimist, Belsomra, estazolam, Brand Lunesta, flurazepam, triazolam, Brand Halcion, Brand Restoril, generic temazepam 7.5 mg and 22.5 mg, generic ramelteon, Brand Rozerem, generic doxepin, Brand Silenor, zaleplon, Quviviq, Dayvigo	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to a trial of at least two of the following preferred agents:*

- Eszopiclone (Generic Lunesta)

- Zolpidem (Generic Ambien)
- Temazepam 15/30 mg (milligram) capsules (Generic Restoril)

AND

2 - For generic ramelteon requests ONLY, patient must have tried and failed Brand Rozerem

Product Name: Brand Ambien, generic zolpidem, Brand Ambien CR, generic zolpidem ER, zolpidem SL, Edluar, Zolpimist, Belsomra, estazolam, generic eszopiclone, Brand Lunesta, flurazepam, triazolam, Brand Halcion, Brand Restoril, generic temazepam, generic ramelteon, Brand Rozerem, generic doxepin, Brand Silenor, zaleplon, Quviviq, Dayvigo	
Diagnosis	Greater than 1 hypnotic in 30 days
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication is being used to adjust the dose of the drug

OR

2 - The requested medication will be used in place of the previously prescribed drug, and not in addition to it

OR

3 - The requested medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

4 - The physician attests they are aware of the multiple sedative hypnotics prescribed to the patient and feels treatment with both medications is medically necessary (Document rationale for use)

Product Name: Brand Ambien, generic zolpidem, Brand Ambien CR, generic zolpidem ER, zolpidem SL, Edluar, Zolpimist, Belsomra, estazolam, generic eszopiclone, Brand Lunesta, flurazepam, triazolam, Brand Halcion, Brand Restoril, generic temazepam, generic ramelteon, Brand Rozerem, generic doxepin, Brand Silenor, zaleplon, Quviviq, Dayvigo	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e., other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary (Document rationale for use)

2 . Revision History

Date	Notes
8/26/2022	C&S to match AZM 10.1.22 that has been updated, removed Interme zzo because it is inactive, cleaned up GPIs and product name lists, cl eaned up punctuations and spelled out abbreviations.

Sensipar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-113750
Guideline Name	Sensipar
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

AND

2 - One of the following:

2.1 Diagnosis of hypercalcemia with parathyroid carcinoma

OR

2.2 All of the following:

2.2.1 Diagnosis of primary hyperparathyroidism (HPT)

AND

2.2.2 Severe hypercalcemia (serum calcium level greater than 12.5 mg/dL) due to primary HPT

AND

2.2.3 Patient is unable to undergo parathyroidectomy

OR

2.3 All of the following:

2.3.1 Diagnosis of secondary hyperparathyroidism with chronic kidney disease

AND

2.3.2 Patient is on dialysis

AND

2.3.3 Both of the following:

2.3.3.1 One of the following:

- Patient has therapeutic failure to ONE phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.) confirmed by claims history or submitted medical records

- Patient has intolerance or contraindication to ONE phosphate binders (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.) (please specify intolerance or contraindication)

AND

2.3.3.2 One of the following:

- Patient has therapeutic failure to ONE vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.) confirmed by claims history or submitted medical records
- Patient has intolerance or contraindication to ONE vitamin D analogs (e.g., calcitriol, Hectorol, Zemplar, etc.) (please specify intolerance or contraindication)

Product Name: Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a reduction in serum calcium from baseline

2 . Revision History

Date	Notes
9/13/2022	Copy NY

Serevent Diskus

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121181
Guideline Name	Serevent Diskus
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Serevent Diskus	
Diagnosis	Asthma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - Patient is 4 years of age or older

AND

3 - Patient is also receiving treatment with an inhaled corticosteroid

Product Name: Serevent Diskus	
Diagnosis	Exercise-Induced Bronchospasm
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of exercise-induced bronchospasm (EIB)

AND

2 - Being used for prevention

AND

3 - Patient is 4 years of age or older

Product Name: Serevent Diskus	
Diagnosis	Bronchospasm associated with chronic obstructive pulmonary disease (COPD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bronchospasm associated with chronic obstructive pulmonary disease (COPD)

2 . Revision History

Date	Notes
2/9/2023	Removed TD criteria section.

SGLT-2 Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137452
Guideline Name	SGLT-2 Inhibitors
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Farxiga	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500 mg (milligrams) daily for 90 days, or contraindication or intolerance to metformin

OR

2 - ONE of the following:

- Diagnosis of chronic kidney disease (CKD)
- Diagnosis of heart failure [NYHA (New York Heart Association) class II-IV] with reduced ejection fraction
- Diagnosis of heart failure (NYHA class II-IV) with preserved ejection fraction

Product Name: Jardiance	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Patient is 10 years of age or older
- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500 mg daily for 90 days, or contraindication or intolerance to metformin

OR

2 - Both of the following:

- Requested medication is being used to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

OR

3 - Requested medication is being used for one of the following:

- To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure

- To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression.

Product Name: Invokana	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - History of failure to metformin at a minimum dose of 1500 mg daily for 90 days, or contraindication or intolerance to metformin

Product Name: Synjardy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - History of failure to metformin at a minimum dose of 1500 mg daily for 90 days, or contraindication or intolerance to metformin

AND

3 - History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana

AND

4 - Patient is 10 years of age or older

Product Name: Invokamet, Invokamet XR, Segluromet, Steglatro, Synjardy XR, Trijardy XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - History of failure to metformin at a minimum dose of 1500 mg daily for 90 days, or contraindication or intolerance to metformin

AND

3 - History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana

Product Name: Xigduo XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500 mg daily for 90 days, or contraindication or intolerance to metformin

OR

2 - ONE of the following:

- Diagnosis of chronic kidney disease (CKD)
- Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

Product Name: Brenzavvy, Glyxambi, Qtern, Steglujan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - History of failure to metformin at a minimum dose of 1500 mg daily for 90 days, or contraindication or intolerance to metformin

AND

3 - History of failure, intolerance, or contraindication to ALL of the following:

- Janumet or Janumet XR
- Januvia

- Jentadueto or Jentadueto XR
- Kombiglyze XR
- Onglyza
- Tradjenta
- Trijardy XR
- Farxiga
- Jardiance
- Invokana

Product Name: Inpefa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication is being used to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with ONE of the following:

- Heart failure
- Type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

AND

2 - History of failure, intolerance, or contraindication to Farxiga

- Farxiga

2 . Revision History

Date	Notes
12/7/2023	Added GPI for Inpefa.

Shingrix (zoster vaccine recombinant, adjuvanted)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116314
Guideline Name	Shingrix (zoster vaccine recombinant, adjuvanted)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Shingrix	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Vaccine is being used for prevention of herpes zoster (shingles)

AND

2 - BOTH of the following:

2.1 Patient is between 18 to 49 years of age* **AND** **2.2** Patient is or will be at increased risk of herpes zoster due to immunodeficiency or immunosuppression caused by known disease or therapy	
Notes	*Prior authorization is not required for patients 50 years of age and older.

2 . Revision History

Date	Notes
11/7/2022	New guideline following FFS.

Short-Acting Opioid Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121363
Guideline Name	Short-Acting Opioid Products
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	2/15/2023

1 . Criteria

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine	
Diagnosis	PA REQUIRED for use of MAT and other Opioids
Guideline Type	DUR

Approval Criteria

1 - Provider attests to notify the prescriber of the MAT(medication-assisted treatment) therapy and the prescriber of the MAT therapy approves the concurrent opioid therapy

AND

2 - The days supply does not exceed 14 days for a surgical procedure

AND

3 - The days supply does not exceed 5 days for all other requests

AND

4 - There has not been a previous approval in the last 6 months

Notes	Approval Length: 14 Days for surgical procedure, 5 Days for all other requests

Product Name: butorphanol nasal soln, codeine sulfate, Brand Fioricet/codeine, Lortab, Brand Xodol, Brand Dilaudid liqd/tabs, Oxaydo, Brand Roxicodone, Nalocet, Endocet, Brand Percocet, Prolate tabs, oxymorphone, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Prolate soln, Qdolo, Seglentis, Roxybond, carisoprodol-aspirin-codeine

Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred* medication, the patient must have a history of failure, contraindication, or intolerance to a trial of at least FIVE of the following preferred short-acting opioids:

- hydromorphone (generic Dilaudid)

• meperidine • morphine sulfate • oxycodone (generic Roxicodone) • tramadol (generic Ultram) • oxycodone w/acetaminophen (generic Percocet) • oxycodone-ibuprofen • acetaminophen w/codeine • butalbital-acetaminophen-caffeine w/codeine (Generic Fioricet) • butalbital-aspirin-caffeine w/cod (generic Fiorinal) • hydrocodone-acetaminophen (generic Norco) • hydrocodone-ibuprofen	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine	
Diagnosis	PA Required for > 2 Short Acting Opioids
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 The requested medication is being used to adjust the dose of the drug

OR

1.2 The requested medication will be used in place of the previously prescribed drug, and not in addition to it

OR

1.3 The requested medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

1.4 The physician attests they are aware of the multiple short-acting opioids prescribed to the patient and feels treatment with all medications is medically necessary (Document rationale for use)

Notes	Authorization will be issued for the requested duration, not to exceed 12 months.

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine

Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - The requested dose cannot be achieved by moving to a higher strength of the product

AND

2 - The requested dose is within FDA (Food and Drug Administration) approved maximum dose per day, where an FDA maximum dose per day exists (See Table 1 in background section)

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine	
Diagnosis	Greater than 5 day supply requests for patients 18 years of age and older
Guideline Type	Quantity Limit
Approval Criteria **1** - ONE of the following conditions or care instances: • Active oncology diagnosis • Hospice care • End-of-life care (other than hospice) • Palliative care • Skilled nursing facility care • Traumatic injury, excluding post-surgical procedures • Chronic conditions for which the provider has received PA (prior authorization) approval • Post-surgical procedures	
Notes	Approvals are for 6 months for all of the listed conditions with the exception of post-surgical procedures which can be approved for a 14 day supply. Adults may obtain additional fills without PA if the refill is requested within 60 days from the initial fill.

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic

tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine	
Diagnosis	Greater than 5 day supply requests for patients under 18 years of age
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following conditions or care instances:

- Active oncology diagnosis
- Hospice care
- End-of-life care (other than hospice)
- Palliative care
- Children on opioid wean at time of hospital discharge
- Skilled nursing facility care
- Traumatic injury, excluding post-surgical procedures
- Chronic conditions for which the provider has received PA (prior authorization) approval
- Post-surgical procedures

Notes	Approvals are for 6 months for all of the listed conditions with the exception of post-surgical procedures which can be approved for a 14 day supply. Children and adolescents may obtain additional fills without PA for 5 days supply unless the submitted PA supports a longer duration for use.

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine	
Diagnosis	Cancer/Hospice/End of Life/Palliative Care/Skilled Nursing Facility/Traumatic Injury Related Pain Exceeding the 90 MME Cumulative Threshold*

Approval Length	12 month(s)
Guideline Type	Morphine Milligram Equivalents (MME) Reviews* (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - ONE of the following conditions:

- Active oncology diagnosis
- Hospice
- End-of-life care (other than hospice)
- Palliative care
- Skilled nursing facility care
- Traumatic injury, including burns and excluding post-surgical procedures

Notes	*The authorization should be entered for an MME of 9999 so as to pre vent future disruptions in therapy if the patient's dose is increased.

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine

Diagnosis	Non-cancer/non-hospice/non-end of life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain Exceeding the 90 MME Cumulative Threshold*
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Prescriber attests to ALL of the following:

1.1 The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested

AND

1.2 Treatment goals are defined, including estimated duration of treatment

AND

1.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

AND

1.4 Patient has been screened for substance abuse/opioid dependence

AND

1.5 If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - BOTH of the following:

- Patient has tried and failed non-opioid pain medication (document drug name and date of trial)
- Opioid medication doses of less than 90 morphine milligram equivalent (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)**

Notes	*Authorization will be issued for 6 months for non-cancer/non-hospice/ non-end-of-life/non-palliative care/non-skilled nursing facility/non-trau matic injury related pain related pain up to the current requested MME

	plus 90 MME. **If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose.

Product Name: butorphanol nasal soln, codeine sulfate, acetaminophen/codeine soln/tabs, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Ascomp/codeine, butalbital/aspirin/caffeine/codeine, morphine sulfate oral soln/supp/tabs, hydrocodone/acetaminophen soln, Lortab, hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, Brand Dilaudid liqd/tabs, generic hydromorphone liqd/supp/tabs, oxycodone caps/conc/soln/tabs, Oxaydo, Brand Roxicodone, Nalocet, oxycodone/acetaminophen tabs/soln, Endocet, Brand Percocet, Prolate tabs/soln, oxymorphone, generic tramadol tabs, Brand Ultram, Synapryn Fusepaq, generic tramadol/acetaminophen, Brand Ultracet, Nucynta, meperidine tabs/oral soln, levorphanol tabs, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium supp, opium tinc, Apadaz, benzhydrocodone/acetaminophen, pentazocine/naloxone, Qdolo, tramadol soln, Seglentis, Roxybond, carisoprodol-aspirin-codeine	
Diagnosis	Non-cancer/non-hospice/non-end of life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain Exceeding the 90 MME Cumulative Threshold*
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Prescriber attests to ALL of the following:

1.1 The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed and the medical information necessary to verify the accuracy of the information provided may be requested

AND

1.2 Treatment goals are defined, including estimated duration of treatment

AND

1.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention **AND** **1.4** Patient has been screened for substance abuse/opioid dependence **AND** **1.5** If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression **AND** **2** - Identify rationale for not tapering and discontinuing opioid (Document rationale) **AND** **3** - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)**	
Notes	*Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain related pain up to the current requested MME plus 90 MME. **If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested MME dose.

2 . Background

Benefit/Coverage/Program Information

Table 1. CDC Recommended Opioid Maximum Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses	90 MME Equivalent (mg/day) (non treatment naïve)
Morphine	None	90mg
Hydromorphone	None	22.5mg
Hydrocodone	None	90mg
Tapentadol	600mg IR products	225mg
Oxymorphone	None	30mg
Oxycodone	None	60mg
Codeine	360mg	600mg
Pentazocine	None	243mg
Tramadol	400mg IR products	900mg
Meperidine	600mg	900mg
Butorphanol	None	12.86mg
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day	90mg
Benzhydrocodone**	None	73.77mg
Levorphanol	None	8.18mg
Acetaminophen	4000 mg	N/A

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

**Morphine Milligram Equivalents is derived from the package insert.

3 . Revision History

Date	Notes
2/15/2023	Updated OR to AND in last section of criteria.

Signifor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64531
Guideline Name	Signifor
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 One of the following:

- Pituitary surgery has not been curative for the patient
- Patient is not a candidate for pituitary surgery

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Signifor therapy

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Siliq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110668
Guideline Name	Siliq
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 Both of the following:

1.1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.5 Patient is not receiving Siliq in combination with ONE of the following:

- Biologic Disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Siliq therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is not receiving Siliq in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Siliq therapy

AND

2 - Patient is not receiving Siliq in combination with one of the following:

- Biologic Disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Simponi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110669
Guideline Name	Simponi
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Simponi	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.3 One of the following:

1.3.1 Patient is receiving concurrent therapy with methotrexate (e.g., Rheumatrex, Trexall)

OR

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.4 History of failure, contraindication, or intolerance to all of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Simponi	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of active ankylosing spondylitis

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Simponi	
Diagnosis	Rheumatoid Arthritis, Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to three of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.5 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with one of the following:

- Rheumatologist

• Dermatologist	
Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Simponi	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Simponi	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis

AND

1.2 One of the following:

1.2.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

OR

1.2.2 History of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

1.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to Humira (adalimumab)

AND

1.5 Prescribed by or in consultation with a gastroenterologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of moderately to severely active ulcerative colitis

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Simponi	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Sivextro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110378
Guideline Name	Sivextro
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Sivextro	
Diagnosis	Skin and Skin Structure Infections
Approval Length	6 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.

OR

1.3 ALL of the following:

1.3.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

1.3.2 ONE of the following diagnoses:

1.3.2.1 BOTH of the following:

- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

1.3.2.2 BOTH of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

AND

1.3.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.3.4 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline

- Clindamycin

OR

1.4 ALL of the following:

1.4.1 Diagnosis of acute bacterial skin and skin structure infection(including diabetic foot infections)

AND

1.4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

AND

1.4.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.4.4 History of failure, contraindication, or intolerance to TWO of the following antibiotics:

- Dicloxacillin
- A cephalosporin
- A tetracycline
- Amoxicillin/clavulanate
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

Product Name: Sivextro	
Diagnosis	Off-Label Uses
Approval Length	60 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 BOTH of the following:

1.3.1 The medication is being prescribed by or in consultation with an infectious disease specialist

AND

1.3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox), if culture and susceptibility confirm susceptibility.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Skyclarys (omaveloxolone)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126400
Guideline Name	Skyclarys (omaveloxolone)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene

AND

2 - Patient is 16 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80

AND

4 - Submission of medical records (e.g., chart notes) confirming patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL (picograms/milliliter)

AND

5 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Neurogeneticist
- Physiatrist (Physical Medicine and Rehabilitation Specialist)

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming positive clinical response to therapy as evidenced by a Modified Friedreich's Ataxia Rating Scale (mFARS) score of less than or equal to 80

2 . Revision History

Date	Notes
6/7/2023	New guideline

Skyrizi (risankizumab-rzaa)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127791
Guideline Name	Skyrizi (risankizumab-rzaa)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 BOTH of the following:

1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Otezla (apremilast)

AND

2 - Prescribed by or in consultation with a dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Skyrizi therapy **AND** **2** - Prescribed by or in consultation with a dermatologist	
Notes	**If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following: **1.1** Diagnosis of active psoriatic arthritis (PsA)	

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz oral tablet (tofacitinib)

AND

2 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Skyrizi therapy

AND

2 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Rheumatologist

Notes	**If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of moderately to severely active Crohn's disease (CD)

AND

1.2 History of failure, contraindication, or intolerance to ONE of the of the following conventional therapies (document drug, date, and duration of trial):*

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroid (e.g., prednisone)

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Cimzia (certolizumab)
- Humira (adalimumab)
- infliximab

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by at least ONE of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Prescribed by or in consultation with a gastroenterologist	
Notes	**If patient meets criteria above, please approve at GPI-14**

2 . Revision History

Date	Notes
7/10/2023	Updated T/F options

Sodium Oxybate Products (Lumryz, Xyrem, Xywav)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126374
Guideline Name	Sodium Oxybate Products (Lumryz, Xyrem, Xywav)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Lumryz, Xyrem, sodium oxybate, Xywav	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

AND

3 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Lumryz, Xyrem, sodium oxybate, Xywav	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a reduction in frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Lumryz, Xyrem, sodium oxybate, Xywav	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Cataplexy is absent

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance of ALL of the following (MUST be verified via paid pharmacy claims or submission of medical records):

3.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.2 Armodafanil (Nuvigil)

AND

3.3 Sunosi (solriamfetol)

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Lumryz, Xyrem, sodium oxybate, Xywav	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Xywav	
Diagnosis	Idiopathic Hypersomnia (IH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of idiopathic hypersomnia (IH) confirmed by ALL of the following:

1.1 Patient has experienced daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months

AND

1.2 A multiple sleep latency test (MSLT) documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was less than or equal to 15 minutes

AND

1.3 The presence of at least ONE of the following:

- MSLT shows a mean sleep latency of less than or equal to 8 minutes
- Total 24-hour sleep time is greater than or equal to 660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log

AND

2 - Physician attestation to BOTH of the following:

2.1 Cataplexy is absent

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

AND

4 - History of failure, contraindication, or intolerance of ALL of the following (MUST be verified via paid pharmacy claims or submission of medical records):

- An amphetamine or methylphenidate based stimulant
- Modafinil
- Amodafinil

Product Name: Xywav	
Diagnosis	Idiopathic Hypersomnia (IH)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting reduction in symptoms of excessive daytime sleepiness associated with therapy

2 . Revision History

Date	Notes
6/8/2023	New program for sodium oxybate products. Replaces Xyrem, Xywav.

Sohonos (palovarotene)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137440
Guideline Name	Sohonos (palovarotene)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Sohonos	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of Fibrodysplasia Ossificans Progressiva (FOP)

AND

1.2 Molecular genetic testing confirms mutation in the ACVR1 gene

AND

1.3 One of the following:

1.3.1 Both of the following:

- Patient is female
- Patient is 8 years of age or older

OR

1.3.2 Both of the following:

- Patient is male
- Patient is 10 years of age or older

AND

2 - Prescribed by or in consultation with one of the following:

- Geneticist
- Orthopedic physician
- Rheumatologist
- Endocrinologist

Product Name: Sohonos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that patient demonstrates positive clinical response to therapy (e.g., reduction of volume in new abnormal bone growth)

2 . Revision History

Date	Notes
12/6/2023	New guideline

Soliris

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128940
Guideline Name	Soliris
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Soliris	
Diagnosis	Atypical hemolytic uremic syndrome (aHUS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation supporting the diagnosis of atypical hemolytic uremic syndrome (aHUS) by ruling out BOTH of the following:

- Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS)*

- Thrombotic thrombocytopenia purpura (TTP) (e.g., rule out ADAMTS13 deficiency)

AND

2 - Laboratory results, signs, and/or symptoms attributed to aHUS (e.g., thrombocytopenia, microangiopathic hemolysis, thrombotic microangiopathy, acute renal failure, etc.)

AND

3 - Patient is treatment naïve with Soliris

AND

4 - Soliris is dosed according to the Food and Drug Administration (FDA) labeled dosing for aHUS

AND

5 - Prescribed by, or in consultation with, a hematologist or nephrologist

Product Name: Soliris	
Diagnosis	Atypical hemolytic uremic syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Documentation demonstrating a positive clinical response from baseline (e.g., reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for atypical hemolytic uremic syndrome (aHUS)

AND

4 - Prescribed by, or in consultation with, a hematologist or nephrologist

Product Name: Soliris	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation supporting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) that includes BOTH of the following:

- Flow cytometry analysis confirming presence of PNH clones
- Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - Patient is treatment naïve with Soliris

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for PNH

AND

4 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name: Soliris	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Documentation demonstrating a positive clinical response from baseline (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in lactate dehydrogenase [LDH], increased reticulocyte count, etc.)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for paroxysmal nocturnal hemoglobinuria (PNH)

AND

4 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name: Soliris	
Diagnosis	Generalized myasthenia gravis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) confirming ALL of the following:

1.1 Patient has not failed a previous course of Soliris therapy

AND

1.2 Positive serologic test for anti-acetylcholine receptor (AChR) antibodies

AND

1.3 ONE of the following:

- History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation
- History of positive anticholinesterase test, e.g., edrophonium chloride test
- Patient has demonstrated improvement in myasthenia gravis (MG) signs on oral cholinesterase inhibitors, as assessed by the treating neurologist

AND

1.4 Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

AND

1.5 Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score greater than or equal to 6 at initiation of therapy

AND

2 - BOTH of the following:

2.1 History of failure of at least TWO immunosuppressive agents over the course of at least 12 months [e.g., azathioprine, methotrexate, cyclosporine, mycophenolate, etc.]

AND

2.2 Patient has required TWO or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least the previous 12 months without symptom control

AND

3 - Patient is currently on a stable therapeutic dose (at least 3 to 6 months) of immunosuppressive therapy

AND

4 - Soliris is initiated and titrated according to the United States Food and Drug Administration (FDA) labeled dosing for gMG: up to a maximum of 1200 milligrams every 2 weeks

AND

5 - Prescribed by, or in consultation, with a neurologist

Product Name: Soliris	
Diagnosis	Generalized myasthenia gravis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by ALL of the following:

- Improvement and/or maintenance of at least a 3 point improvement (reduction in score) in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score from pre-treatment baseline
- Reduction in signs and symptoms of myasthenia gravis
- Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Soliris (Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for generalized myasthenia gravis (gMG): up to a maximum of 1200 milligrams every 2 weeks

AND

4 - Prescribed by, or in consultation, with a neurologist

Product Name: Soliris	
Diagnosis	Neuromyelitis optica spectrum disorder (NMOSD)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirming ALL of the following:

1.1 Past medical history of ONE of the following:

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

AND

1.2 Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies

AND

1.3 Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

2 - Patient has not failed a previous course of Soliris therapy

AND

3 - History of failure of, contraindication, or intolerance to rituximab (Rituxan, Ruxience, Truxima) therapy

AND

4 - One of the following:

4.1 History of at least two relapses during the previous 12 months prior to initiating Soliris

OR

4.2 History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris

AND

5 - Soliris is initiated and titrated according to the U.S. FDA labeled dosing for NMOSD, up to a maximum of 1200 mg every 2 weeks

AND

6 - Prescribed by, or in consultation with, a neurologist

AND

7 - Patient is NOT receiving Soliris in combination with one of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Anti-IL6 (interleukin 6) therapy [e.g., Actemra (tocilizumab)]

Product Name: Soliris	
Diagnosis	Neuromyelitis optica spectrum disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by BOTH of the following:

2.1 Reduction in the number and/or severity of relapses or signs and symptoms of neuromyelitis optica spectrum disorder (NMOSD)

AND

2.2 Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting Soliris. (Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure)

AND

3 - Soliris is dosed according to the U.S. FDA (Food and Drug Administration) labeled dosing for NMOSD: up to a maximum of 1200 mg every 2 weeks

AND

4 - Prescribed by, or in consultation with, a neurologist

AND

5 - Patient is not receiving Soliris in combination with one of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Anti-IL6 (interleukin 6) therapy [e.g., Actemra (tocilizumab)]

2 . Revision History

Date	Notes
7/25/2023	Updated GPI

Somavert

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64532
Guideline Name	Somavert
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Somavert	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of acromegaly by ONE of the following:

- Serum GH (growth hormone) level greater than 1 ng/mL (nanograms per milliliter) after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
- Elevated serum IGF-1 (Insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

AND

1.2 One of the following:

1.2.1 Inadequate response to one of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

1.2.2 Not a candidate for all of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

1.3 Inadequate response, intolerance, or contraindication to one of the following somatostatin analogs:

- Sandostatin (octreotide) or Sandostatin LAR
- Somatuline Depot (lanreotide)

OR

2 - Patient is currently on Somavert therapy for acromegaly

Product Name: Somavert	
Diagnosis	Acromegaly

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Somavert therapy

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Soriatane

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110320
Guideline Name	Soriatane
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Soriatane, Generic acitretin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe psoriasis

AND

2 - Prescribed or recommended by a dermatologist

AND

3 - One of the following:

3.1 Patient is unresponsive to other therapies (e.g., topical corticosteroids, topical vitamin D analogs, tazarotene, methotrexate)

OR

3.2 Other therapies are contraindicated based on the patient's clinical condition

AND

4 - One of the following:

- Greater than or equal to 10% body surface area involvement
- Palmoplantar, facial, or genital involvement
- Severe scalp psoriasis

Product Name: Brand Soriatane, Generic acitretin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Soriatane therapy

AND

2 - Prescribed or recommended by a dermatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Sotyktu (deucravacitinib)

Prior Authorization Guideline

Guideline ID	GL-121059
Guideline Name	Sotyktu (deucravacitinib)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of moderate to severe plaque psoriasis

AND

2 - Submission of medical records (e.g., chart notes) confirming ONE of the following:

- At least 3% body surface area (BSA) involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - BOTH of the following (verified via submission of records or paid pharmacy claims):

5.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Enbrel (etanercept)
- Humira (adalimumab)

AND

5.2 Trial and failure, contraindication, or intolerance to Otezla (apremilast)

AND

6 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine)

Product Name: Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming positive clinical response to therapy as evidenced by ONE of the following:

- Reduction of the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine)

2 . Revision History

Date	Notes
2/7/2023	Updated T/F criteria to Otezla.

Spinraza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110687
Guideline Name	Spinraza
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Spinraza	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) type I, II, or III made by, or in consultation with, a neurologist with expertise in the diagnosis of SMA

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following:

- Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on use of non-invasive ventilation beyond use for naps and nightime sleep

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) or claims history of the baseline exam of one of the following exams (based on patient age and motor ability) to establish baseline motor ability:

- Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test (Non ambulatory)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)

AND

6 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA

AND

7 - One of the following:

7.1 Patient has not previously received gene replacement therapy for the treatment of SMA

OR

7.2 One of the following:

7.2.1 Both of the following:

7.2.1.1 Patient recently received gene replacement therapy within the previous 6 months

AND

7.2.1.2 Patient has experienced a declination in clinical status since receipt of gene replacement therapy

OR

7.2.2 Both of the following:

7.2.2.1 Patient has previously received gene replacement therapy

AND

7.2.2.2 Patient has experienced a declination in clinical status that represents a potential abatement of gene therapy efficacy

AND

8 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures

AND

9 - Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12 milligrams for each loading dose

Product Name: Spinraza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) type I, II, or III made by, or in consultation with, a neurologist with expertise in the diagnosis of SMA

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history confirming both of the following:

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following:

- Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on use of non-invasive ventilation beyond use for naps and nightime sleep

AND

5 - One of the following:

5.1 Patient has not previously received gene replacement therapy for the treatment of SMA

OR

5.2 Both of the following:

5.2.1 Patient has previously received gene replacement therapy

AND

5.2.2 Patient has experienced a declination in clinical status that represented a potential failure or abatement of gene therapy efficacy

AND

6 - Submission of medical records (e.g., chart notes, laboratory values) or claims history with the most recent results (less than 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by one of the following exams:

6.1 Both of the following for Hammersmith Infant Neurological Exam Part 2 (HINE-2) milestones:

6.1.1 One of the following:

- Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick

- Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp

AND

6.1.2 One of the following:

- The patient exhibited improvement or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

6.2 One of the following for Hammersmith Functional Motor Scale Expanded (HFMSE):

- Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.3 One of the following for Upper Limb Module (ULM):

- Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.4 One of the following for Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND):

6.4.1 Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline

OR

6.4.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.4.3 Both of the following:

- Patient was prescribed Spinraza due to clinical declination after receipt of gene therapy
- Patients clinical status has stabilized after receipt of Spinraza therapy

AND

7 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA

AND

8 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures

AND

9 - Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12 milligrams every 4 months, starting 4 months after the last loading dose

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Spravato, ketamine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136051
Guideline Name	Spravato, ketamine
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Spravato, ketamine	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a confirmed diagnosis of major depressive disorder as defined by the DSM-V (Diagnostic and Statistical Manual of Mental Disorders) criteria and is treatment resistant

AND

2 - Patient is 18 years of age or older

AND

3 - Requested medication is prescribed by, or in consultation with, a psychiatric provider

AND

4 - ONE of the following:

4.1 Patient does not have an active substance use disorder (SUD)

OR

4.2 BOTH of the following:

- Patient has an active substance use disorder
- Patient is currently receiving treatment

AND

5 - ONE of the following:

5.1 Patient has experienced an inadequate response during the current depressive episode with BOTH of the following therapies:

5.1.1 Two antidepressants from at least two different classes [must include one of each AHCCCS (Arizona Health Care Cost Containment System) preferred agents: SSRI (selective serotonin reuptake inhibitor), SNRI (serotonin-norepinephrine reuptake inhibitor), or bupropion] having different mechanisms of action at the maximally tolerated labeled dose, each used for at least 4-6 weeks

AND

5.1.2 At least TWO augmentation therapies below for at least 4 weeks:

- SSRI or SNRI, and a second-generation antipsychotic used concomitantly (aripiprazole, quetiapine, risperidone, olanzapine)
- SSRI or SNRI, and lithium used concomitantly
- SSRI or SNRI, and liothyronine (T3) used concomitantly
- SSRI or SNRI, and mirtazapine
- SSRI and bupropion and buspirone

OR

5.2 Patient has active suicidal ideation and urgent symptom control is necessary

AND

6 - Requested medication is used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)

AND

7 - Requested medication is administered under the direct supervision of a healthcare provider

AND

8 - Provider is certified in the Spravato REMS (risk evaluation and mitigation strategy) program (Applies to Spravato requests ONLY)

AND

9 - Patient must be monitored by a health care provider for at least 2 hours after administration

Product Name: Spravato, ketamine	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has documented improvement or sustained improvement in depressive symptoms from baseline

AND

2 - Patient use of requested medication is in combination with an oral antidepressant

AND

3 - Patient administers requested medication under the direct supervision of a healthcare provider

AND

4 - Provider is certified in the Spravato REMS (risk evaluation and mitigation strategy) program (applies to Spravato requests ONLY)

AND

5 - Patient must continue to be monitored by a health care provider for at least 2 hours after administration

Product Name: Spravato, ketamine	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

Product Name: Spravato, ketamine	
Diagnosis	Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5) criteria

AND

2 - Patient is experiencing an acute suicidal ideation or behavior

AND

3 - Patient is receiving newly initiated or optimized oral antidepressant

AND

4 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program (applies to Spravato requests ONLY)

2 . Revision History

Date	Notes
11/7/2023	Added GPIs for injectable ketamine, updated criteria to reflect additio nal targets.

Stelara

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116077
Guideline Name	Stelara
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 ONE of the following:

1.1.7.1 Requested medication is Stelara 45 mg (milligrams) per 0.5 mL (milliliter)

OR

1.1.7.2 BOTH of the following:

- Requested medication is Stelara 90 mg per 1 mL
- Patient's weight is greater than 100 kg (kilograms) (220 pounds)

AND

1.1.8 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

AND

2 - Patient is 6 years of age or older

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 ONE of the following

1.1.1.1 BOTH of the following:

- Requested medication is Stelara 45 mg (milligrams) per 0.5 mL (milliliter)
- Diagnosis of active psoriatic arthritis

OR

1.1.1.2 ALL of the following:

- Diagnosis of active psoriatic arthritis
- Diagnosis of co-existent moderate to severe plaque psoriasis

AND

1.1.2 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.3 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to three of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

AND

2 - Patient is 6 years of age or older

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following:

2.1 Both of the following

2.1.1 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

AND

2.1.2 History of failure, contraindication or intolerance to Humira (adalimumab)

OR

2.2 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

2.1 Both of the following

2.1.1 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

2.1.2 History of failure, contraindication or intolerance to Humira (adalimumab)

OR

2.2 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara (all subcutaneous strengths)

Diagnosis	Crohn's Disease, Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
10/25/2022	Added age criterion for PsA and PsO. Added all SC formulations for Chron's.

Strensiq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110624
Guideline Name	Strensiq
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Strensiq	
Diagnosis	perinatal/infantile or juvenile-onset hypophosphatasia (HPP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on all of the following:

1.1.1 One of the following:

- Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)
- Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 years (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

AND

1.1.2 One of the following:

1.1.2.1 Both of the following:

- Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age-adjusted normal range
- Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

OR

1.1.2.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing*

AND

1.2 Prescribed by one of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

AND

1.3 One of the following:

1.3.1 Both of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

OR

1.3.2 Both of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

AND

1.4 One of the following:

1.4.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

1.4.2 Both of the following:

- Patient is prescribed Strensiq 80 mg/0.8 mL vial
- Patient's weight is greater than or equal to 40 kg

AND

1.5 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering

Product Name: Strensiq	
Diagnosis	perinatal/infantile or juvenile-onset hypophosphatasia (HPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

AND

1.2 Prescribed by one of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone diseases

AND

1.3 One of the following:

1.3.1 Both of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

OR

1.3.2 Both of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

AND

1.4 One of the following:

1.4.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

1.4.2 Both of the following

- Patient is prescribed Strensiq 80 mg/0.8 mL vials
- Patient's weight is greater than or equal to 40 kg

AND

1.5 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Sublingual Immunotherapy (SLIT)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-122992
Guideline Name	Sublingual Immunotherapy (SLIT)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Grastek, Oralair, Ragwitek, Odactra	
Diagnosis	Patients 21 years of age and older
Approval Length	N/A - All requests for patients 21 years of age and older should be DENIED as benefit exclusion
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for patients 21 years of age and older are not covered	
Notes	Approval Length: N/A - All requests for patients 21 years of age and older should be denied as a benefit exclusion.

Product Name: Grastek	
Diagnosis	Grass pollen-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)
- In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to TWO of the following:

- Oral antihistamine [e.g., cetirizine (Zyrtec)]
- Intranasal antihistamine [e.g., azelastine (Astelin)]
- Intranasal corticosteroid [e.g., fluticasone (Flonase)]
- Leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Grastek	
Diagnosis	Grass pollen-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Grastek therapy

Product Name: Oralair	
Diagnosis	Grass pollen-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]
- In vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]

AND

3 - Treatment is started or will be started at least 4 months before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to TWO of the following:

- Oral antihistamine [e.g., cetirizine (Zyrtec)]
- Intranasal antihistamine [e.g., azelastine (Astelin)]
- Intranasal corticosteroid [e.g., fluticasone (Flonase)]
- Leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Grastek)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Oralair	
Diagnosis	Grass pollen-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oralair therapy

Product Name: Ragwitek	
Diagnosis	Short ragweed pollen-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to short ragweed pollen

- In vitro testing for pollen-specific IgE antibodies for short ragweed pollen

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

AND

4 - History of failure, contraindication, or intolerance to TWO of the following:

- Oral antihistamine [e.g., cetirizine (Zyrtec)]
- Intranasal antihistamine [e.g., azelastine (Astelin)]
- Intranasal corticosteroid [e.g., fluticasone (Flonase)]
- Leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Patient does not have unstable and/or uncontrolled asthma

AND

6 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Ragwitek	
Diagnosis	Short ragweed pollen-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ragwitek therapy

Product Name: Odactra	
Diagnosis	House dust mite (HDM)-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of house dust mite (HDM)-induced allergic rhinitis

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to licensed house dust mite allergen extracts
- In vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites

AND

3 - History of failure, contraindication, or intolerance to TWO of the following:

- Oral antihistamine [e.g., cetirizine (Zyrtec)]
- Intranasal antihistamine [e.g., azelastine (Astelin)]
- Intranasal corticosteroid [e.g., fluticasone (Flonase)]
- Leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

4 - Patient does not have unstable and/or uncontrolled asthma

AND

5 - Prescribed by or in consultation with a specialist in allergy and immunology

AND

6 - Patient is at least 12 years of age and not greater than 20 years of age

Product Name: Odactra	
Diagnosis	House dust mite (HDM)-induced allergic rhinitis for patients under 21 years of age
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Odactra therapy

AND

2 - Patient is at least 12 years of age and not greater than 20 years of age

2 . Revision History

Date	Notes
3/14/2023	Added age criteria for Odactra, cleaned up GPI list for Oralair, updated indications to include age restriction, cleaned up criteria.

Sublocade

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137456
Guideline Name	Sublocade
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Sublocade	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has severe Opioid Use Disorder (OUD) as defined by the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) OUD Diagnostic Tool and has a demonstrated history of non-adherence to oral medications

AND

2 - Patient is currently maintained on 8 mg (milligrams) to 24 mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection

AND

3 - Patient will not receive supplemental oral, sublingual, or transmucosal buprenorphine

AND

4 - Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program

AND

5 - Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection

AND

6 - Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: 300 mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg or 300 mg monthly

Product Name: Sublocade	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician documentation that the patient has experienced a positive clinical response to buprenorphine extended-release therapy, as defined by the provider

AND

2 - Patient will not receive supplemental oral, sublingual, or transmucosal buprenorphine

AND

3 - Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program

AND

4 - Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection

AND

5 - Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: maintenance dose of 100 mg (milligrams) or 300 mg monthly

2 . Revision History

Date	Notes
12/7/2023	Updated verbiage for supplemental buprenorphine throughout criteria .

Suboxone

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116072
Guideline Name	Suboxone
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Generic buprenorphine-naloxone film, Zubsolv *	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a Diagnostic and Statistical Manual, Fifth Edition, Text Revision, (DSM-V-TR) diagnosis of opioid use disorder

AND

2 - The patient must have a reason or special circumstance that they cannot use the preferred products **

- brand Suboxone Film
- buprenorphine (generic Subutex)
- buprenorphine HCl/naloxone Tab (Generic Suboxone Tab)
- naloxone
- naltrexone
- Narcan (naloxone)
- Sublocade (buprenorphine)
- Vivitrol (naltrexone microspheres)

Notes	*Up to 24 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the initial period **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Generic buprenorphine-naloxone film, Zubsolv *	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been prescribed a buprenorphine product for the purpose of opioid use disorder maintenance therapy

AND

2 - The patient must have a reason or special circumstance that they cannot use the preferred products**

AND

3 - Patient must have tried Suboxone film or buprenorphine-naloxone ODT tablets

Notes	*Up to 16 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the reauthorization period

	**PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Brand suboxone, generic buprenorphine-naloxone film, buprenorphine/naloxone sublingual tablet, Zubsolv *	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Quantity Limit
Approval Criteria **1** - Physician has provided rationale for needing to exceed the buprenorphine daily limit **AND** **2** - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation	
Notes	* This criteria applies to requests exceeding 24 mg of buprenorphine or equivalent

Product Name: Brand suboxone, generic buprenorphine-naloxone film, buprenorphine/naloxone sublingual tablet, Zubsolv *	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Quantity Limit
Approval Criteria **1** - Physician has provided rationale for needing to exceed the buprenorphine daily limit **AND**	

2 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation	
Notes	*This criteria applies to requests exceeding 16 mg of buprenorphine or equivalent

2 . Revision History

Date	Notes
10/28/2022	Updated GL name and GPIs to be complete. Updated NP criteria to add generic buprenorphine-naloxone film. Updated PDL links.

Sucraid

Prior Authorization Guideline

Guideline ID	GL-110625
Guideline Name	Sucraid
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Sucraid	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital sucrase-isomaltase deficiency (CSID) as confirmed by one of the following:

1.1 Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides

OR

1.2 All of the following:

- Stool pH less than 6
- Negative lactose breath test
- Increase in breath hydrogen greater than 10 ppm (parts per million) when challenged with sucrose after fasting

AND

2 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

3 - Will be used with a sucrose-free, low starch diet

Product Name: Sucraid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

2 - Will be used with a sucrose-free, low starch diet

AND

3 - Provider attests that the patient has achieved a clinically meaningful response while on Sucraid therapy, defined as at least a 50 percent reduction in all of the following:

- Symptoms of abdominal pain, cramps, bloating, gas, vomiting
- Number of stools per day
- Watery, loose stool consistency
- Number of symptomatic days

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Sunlenca

Prior Authorization Guideline

Guideline ID	GL-122927
Guideline Name	Sunlenca
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Sunlenca	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes) documenting all of the following:

1.1.1 Diagnosis of HIV-1 infection

AND

1.1.2 Both of the following:

1.1.2.1 Patient is heavily treatment-experienced with multidrug resistance as confirmed by a resistance assay

AND

1.1.2.2 Patient is failing their current antiretroviral regimen due to ONE of the following:

- Resistance
- Intolerance
- Safety considerations

AND

1.1.3 Patient is currently taking, or will be prescribed, an active and optimized background antiretroviral therapy regimen

AND

1.1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

2 . Revision History

Date	Notes
3/9/2023	New

Sunosi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110336
Guideline Name	Sunosi
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

OR

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a multiple sleep latency test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

AND

2 - Physician attestation to the following:

- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance to BOTH of the following:

3.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.2 Armodafinil

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of obstructive sleep apnea with ONE of the following:

1.1 Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study

OR

1.2 BOTH of the following:

1.2.1 Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study

AND

1.2.2 ONE or more of the following sign/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by bed partner or other observer
- Observed apnea

AND

2 - BOTH of the following:

2.1 Standard treatments for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - History of failure, contraindication, or intolerance to armodafinil

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g. continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP])

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Sutent

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110721
Guideline Name	Sutent
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - History of failure, contraindication, or intolerance to Gleevec (imatinib)

Product Name: Sutent	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 Diagnosis of Stage IV disease

OR

2.3 BOTH of the following:

2.3.1 Used in adjuvant setting

AND

2.3.2 Patient has a high risk of recurrence following nephrectomy

Product Name: Sutent

Diagnosis	Islet Cell Tumor / Progressive Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of islet cell tumor / progressive pancreatic neuroendocrine tumors (pNET)

AND

2 - Disease is ONE of the following:

- Unresectable, locally advanced
- Metastatic

Product Name: Sutent	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma (ASPS)
- Angiosarcoma
- Solitary fibrous tumor / hemangiopericytoma

Product Name: Sutent	
Diagnosis	Thyroid Carcinoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 Disease is refractory to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Patient has progressive disease
- Patient has symptomatic metastatic disease

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Sutent	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name: Sutent	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of surgically inaccessible meningiomas

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

3 - Further radiation is not possible

Product Name: Sutent	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

AND

2 - Used as second-line following a failure, contraindication, or intolerance to a first-line chemotherapy regimen (e.g., carboplatin/paclitaxel)

Product Name: Sutent

Diagnosis	Gastrointestinal Stromal Tumor (GIST), Renal Cell Carcinoma (RCC), Islet Cell Tumor / Progressive Pancreatic Neuroendocrine Tumors (pNET), Soft Tissue Sarcoma, Thyroid Carcinoma, Chordoma, Central Nervous System Cancer, Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Product Name: Sutent	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Sutent will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Sutent	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sutent therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Symdeko

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110626
Guideline Name	Symdeko
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Symdeko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory result documenting ONE of the following:

2.1 The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

OR

2.2 The patient has at least ONE mutation in the CFTR gene that is responsive to Symdeko (See Table in Background Section)

AND

3 - The patient is greater than or equal to 6 years of age

AND

4 - Prescribed by or in consultation with a specialist affiliated with a CF care center

Product Name: Symdeko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Symdeko therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Background

Benefit/Coverage/Program Information
Table 1 CFTR Gene Mutations

A1067T	D1270N	F1052V	R1070W	S945L	3272-26A→G
A455E	D579G	F1074L	R117C	S977F	3849+10kbC→T
D110E	E193K	K1060T	R347H		711+3A→G
D110H	E56K	L206W	R352Q		2789+5G→A
D1152H	E831X	P67L	R74W		

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Symlin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64413
Guideline Name	Symlin
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Symlin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have ONE of the following diagnoses:

- Type 1 diabetes
- Type 2 diabetes

AND

2 - Concurrent use of insulin therapy

2 . Revision History

Date	Notes
3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Synagis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117941
Guideline Name	Synagis
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2023

Note:

PA is not required for children under 2 years of age

1 . Criteria

Product Name: Synagis*	
Diagnosis	Prematurity
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is an infant born before 29 weeks, 0 days gestation

AND

1.2 Patient is less than 12 months of age at the start of RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

• Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Chronic Lung Disease (CLD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following for patients age 0 to less than 12 months:

1.1.1 The patient is a preterm infant defined as gestational age less than 32 weeks, 0 days

AND

1.1.2 Patient has developed chronic lung disease (CLD) of prematurity

AND

1.1.3 There was a requirement for greater than 21% oxygen for at least the first 28 days after birth

OR

1.2 ALL of the following for patients age greater than or equal to 12 months to less than 24 months:

1.2.1 The patient was born at less than 32 weeks, 0 days gestation

AND

1.2.2 The patient required at least 28 days of oxygen after birth

AND

1.2.3 The patient continues to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy

• Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present] • Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present) • Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab • Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children • Synagis prophylaxis for prevention of nosocomial disease • Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital Heart Disease (CHD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following for patients age 0 to less than 12 months:

1.1.1 Patient has hemodynamically significant congenital heart disease (CHD) including ONE of the following:

- Acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures
- Moderate to severe pulmonary hypertension

- Documentation that decisions regarding prophylaxis for infants with cyanotic heart defects were made in consultation with a pediatric cardiologist

OR

1.1.2 The patient is undergoing cardiac transplantation during the RSV "season"

OR

1.2 BOTH of the following:

1.2.1 The patient is greater than or equal to 12 months to less than 24 months of age:

AND

1.2.2 ONE of the following:

- After cardiac bypass
- At the conclusion of extracorporeal membrane oxygenation
- The patient is undergoing cardiac transplantation during the RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital abnormalities of the airway or neuromuscular disease
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient is age 0 to less than 12 months

AND

1.2 Patient has ONE of the following:

- Neuromuscular disease
- A congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)

• Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab • Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children • Synagis prophylaxis for prevention of nosocomial disease • Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Immunocompromised children less than 24 months of age
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is less than 24 months of age

AND

1.2 The patient is immunocompromised (e.g. receiving cancer chemotherapy, undergoing hematopoietic stem cell transplantation, or solid organ transplantation)

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV "season" ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th

	e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Cystic fibrosis (CF)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following for patients age 0 to less than 12 months:

1.1.1 Patient has cystic fibrosis

AND

1.1.2 Patient has clinical evidence of at least ONE of the following:

- Chronic lung disease (CLD)
- Nutritional compromise
- Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart

OR

1.2 BOTH of the following:

1.2.1 Patient is greater than or equal to 12 months to less than 24 months of age

AND

1.2.2 Patient has manifestations of severe lung disease including ONE of the following:

- Previous hospitalization for pulmonary exacerbation in the first year of life
- Abnormalities on chest radiography or chest computed tomography that persists when stable

- Weight for length less than the 10th percentile on a pediatric growth chart

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV "season" ** Information regarding RSV season may be found at:

	• Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV "season," fewer than 5 monthl y doses may be needed.

2 . Background

Benefit/Coverage/Program Information
Additional Information In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of Synagis administration. [10] • Despite varied onsets, the RSV "season" is of the same duration (5 months) in the different regions of Florida. • On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants. • Limited information is available concerning the burden of RSV disease among Native American populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life. For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% and RSV "season" offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is ≥ 10%. Use of specimens

to determine the start of the RSV “season” requires that the number of specimens tested be statistically significant.

3 . Revision History

Date	Notes
12/8/2022	Added guideline note for PA is not required if patient is under 2 years of age.

Systane, Refresh, Gonak, Genteal, Tears Naturale

Prior Authorization Guideline

Guideline ID	GL-110345
Guideline Name	Systane, Refresh, Gonak, Genteal, Tears Naturale
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: brand Systane, brand Refresh, brand Gonak, brand Genteal, Tears Naturale	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following:

- Generic equivalents for drops, ointments and gel formulations for Systane, Refresh, Gonak, Genteal, Tears Naturale, and Generic equivalent to the requested brand product
- sodium chloride ophthalmic ointment

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Talicia and Mycobutin

Prior Authorization Guideline

Guideline ID	GL-110283
Guideline Name	Talicia and Mycobutin
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Mycobacterium Avium Complex Prophylaxis

AND

2 - Prescribed by or in consultation with an HIV or infectious disease specialist

AND

3 - Member has failed azithromycin or clarithromycin or is intolerant to the medication due to significant adverse effects or both are contraindicated

AND

4 - If request is for brand Mycobutin and the member is allergic to the generic formulation, the prescriber must submit the FDA MedWatch form

AND

5 - The requested dosage does not exceed 450 mg per day

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member is responding positively to therapy

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - For doses that exceed 450mg, the use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- • United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

Product Name: Mycobutin	
Diagnosis	Helicobacter pylori Infection (off-label)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of H. pylori infection

AND

2 - Prescribed in combination with amoxicillin and a proton pump inhibitor

AND

3 - If request is for brand Mycobutin, inability to use generic rifabutin (e.g., contraindications to excipients in rifabutin)

Product Name: Talicia	
Diagnosis	Helicobacter pylori Infection
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of H. pylori infection

AND

2 - The medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist

AND

3 - One of the following:

3.1 Member has tried 3 first-line treatment regimens listed in the table in background section (One of which must be Rifabutin triple therapy)

OR

3.2 Both of the following:

3.2.1 Culture and sensitivity report indicate resistance or lack of susceptibility of H. pylori to all first-line treatment regimens except Rifabutin triple therapy

AND

3.2.2 Member must have tried and failed Rifabutin triple therapy

Product Name: Mycobutin	
Diagnosis	Tuberculosis (off-label)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberculosis infection

AND

2 - Prescribed by or in consultation with an HIV or infectious disease specialist

AND

3 - Current treatment with protease inhibitors or non-nucleoside reverse transcriptase inhibitors (NNRTIs) for the treatment of HIV infection

AND

4 - If the request is for brand Mycobutin, inability to use generic rifabutin (e.g., contraindications to excipients in rifabutin).

Product Name: Mycobutin	
Diagnosis	Tuberculosis (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member is responding positively to therapy

2 . Background

Benefit/Coverage/Program Information

Dosing Table

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Azithromycin	**MAC:** 1,200 mg PO once weekly or 600 mg PO twice weekly	500 mg/day
Clarithromycin	**MAC:** 500 mg PO BID	1.5 g/day
clarithromycin triple regimen	***H. pylori* infection:** 14 days: PPI (standard or double dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg or metronidazole 500 mg TID (if penicillin allergy)	See dosing regimen
bismuth quadruple regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; bismuth subcitrate (120-300 mg) or subsalicylate (300 mg) QID; tetracycline 500 mg QID; metronidazole 250 mg QID or 500 mg TID-QID	See dosing regimen
concomitant regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg; Metronidazole or tinidazole 500 mg	See dosing regimen
sequential regimen	***H. pylori* infection:** 5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, clarithromycin 500 mg + metronidazole/tinidazole	See dosing regimen
hybrid regimen	***H. pylori* infection:**	See dosing regimen

	7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 7 days of BID PPI, amoxicillin + clarithromycin 500 mg + metronidazole/tinidazole	
levofloxacin triple regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; levofloxacin 500 mg QD; amoxicillin 1,000 mg BID	See dosing regimen
levofloxacin sequential regimen	***H. pylori* infection:**	See dosing regimen
	5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, amoxicillin + metronidazole/tinidazole + QD levofloxacin 500 mg	
rifabutin triple	***H. pylori* infection:** 10 days of BID PPI (standard dose) + amoxicillin 1,000 mg BID + rifabutin 300 mg QD	See dosing regimen

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Taltz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110749
Guideline Name	Taltz
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 BOTH of the following:

1.1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following nonpreferred biologic products (document drug, date, and duration of trial): *

- Cimzia

AND

1.1.6 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukin umab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active psoriatic arthritis

AND

1.1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)*

AND

1.1.3 History of failure, contraindication, or intolerance to THREE of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.4 History of failure, contraindication, or intolerance to THREE of the following non-preferred biologic products (document drug, date, and duration of trial):*

- Orencia
- Cimzia
- Simponi

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist

- Dermatologist

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active ankylosing spondylitis

AND

1.1.2 History of failure to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.3 History of failure, contraindication, or intolerance to BOTH of the following preferred biologic products (document drug, date, and duration of trial):

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.4 History of failure, contraindication, or intolerance to BOTH of the following non-preferred biologic products (document drug, date, and duration of trial):*

- Cimzia
- Simponi

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with a rheumatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active ankylosing spondylitis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND **1.2.4** Prescribed by or in consultation with a rheumatologist	
Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Taltz	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.1.2 History of failure, contraindication, or intolerance to BOTH of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.3 History of failure, contraindication, or intolerance to BOTH of the following nonpreferred biologic products (document drug, date, and duration of trial):*

- Cimzia
- Simponi

AND

1.1.4 History of failure to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.1.6 Prescribed by or in consultation with a rheumatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz

Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Targretin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110724
Guideline Name	Targretin
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - History of failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g. Interferons])

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has not had disease progression while on therapy

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Targretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Targretin therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Tarpeyo (budesonide)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116073
Guideline Name	Tarpeyo (budesonide)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine

ratio (UPCR) greater than or equal to 1.5 g/g (gram), or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2 (milliliters/minute/1.73 square meters)

AND

5 - One of the following:

5.1 Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following:

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to both ACE inhibitors and ARBs

AND

6 - Trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone)

AND

7 - Prescribed by or in consultation with a nephrologist

2 . Revision History

Date	Notes
10/28/2022	Removed references and updated abbreviations, no clinical criteria c hanges.

Tasmar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124762
Guideline Name	Tasmar
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: generic tolcapone, Brand Tasmar	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and

will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

3 - ONE of the following:

3.1 Failure to TWO of the following anti-Parkinson's disease adjunctive pharmacotherapy classes (trial must be from TWO different classes) as confirmed by claims history or submission of medical records:

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

OR

3.2 History of intolerance or contraindication to ALL of the following anti-Parkinson's disease adjunctive pharmacotherapy classes (please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

AND

4 - Patient has received baseline liver function tests to rule out the presence of underlying liver disease

AND

5 - Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

AND

6 - Prescriber attests they have had complete discussion with the patient about the risks and benefits of Tasmar (tolcapone) use, including the risk of liver failure

Product Name: generic tolcapone, Brand Tasmar	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tasmar (tolcapone) therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

AND

3 - Patient has received periodic evaluation of liver function tests to rule out liver failure associated with Tasmar (tolcapone) use

Tavneos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121822
Guideline Name	Tavneos
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Tavneos	
Diagnosis	ANCA (Anti-Neutrophil Cytoplasmic Autoantibody)-Associated Vasculitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe active ANCA (anti-neutrophil cytoplasmic autoantibody)-associated vasculitis

AND

2 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the disease is ONE of the following types:

2.1 Granulomatosis with polyangiitis (GPA)

OR

2.2 Microscopic polyangiitis (MPA)

AND

3 - Patient is being treated with an initial immunosuppressive regimen to induce remission (i.e., rituximab, cyclophosphamide)

AND

4 - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g., prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

AND

5 - Prescribed by ONE of the following:

- Rheumatologist
- Nephrologist
- Pulmonologist
- Vascular Medicine Specialist

Product Name: Tavneos	
Diagnosis	ANCA (Anti-Neutrophil Cytoplasmic Autoantibody)-Associated Vasculitis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tavneos therapy

AND

2 - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g., prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Nephrologist
- Pulmonologist
- Vascular Medicine Specialist

Tecartus

Prior Authorization Guideline

Guideline ID	GL-127910
Guideline Name	Tecartus
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Tecartus	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory mantle cell lymphoma

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has been treated with ALL of the following:

- An anthracycline or bendamustine-containing chemotherapy
- Anti-CD20 monoclonal antibody therapy (e.g., rituximab)
- A Bruton tyrosine kinase (BTK) inhibitor indicated for mantle cell lymphoma (e.g., acalabrutinib, ibrutinib, zanubrutinib)

AND

4 - Disease progression has occurred following the last regimen or disease is refractory to the most recent therapy

AND

5 - The patient has received or will receive a lymphodepleting chemotherapy regimen consisting of BOTH of the following on each of the fifth, fourth, and third days before infusion of Tecartus:

- Cyclophosphamide 500 milligrams/square meter (mg/m^2) intravenously
- Fludarabine 30 mg/m^2 intravenously

AND

6 - Patient will not be treated with more than 2 x 10^8 CAR (chimeric antigen receptor)-positive viable T cells

AND

7 - The patient has not received prior treatment with CAR T-cell therapy

AND

8 - If the patient has had a prior allogeneic HSCT (haematopoietic stem cell transplantation), the patient does not currently have active GVHD (graft-versus-host disease)

AND

9 - The treating facility is certified under the Tecartus Risk Evaluation and Mitigation Strategy (REMS) System Program

Product Name: Tecartus	
Diagnosis	Acute Lymphocytic Leukemia (ALL)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AND

2 - Patient is 18 years of age or older

AND

3 - ONE of the following:

- Has primary refractory disease
- Is in first relapse with remission of 12 months or less
- Relapsed or refractory after at least two previous lines of systemic chemotherapy
- Relapsed or refractory after allogeneic stem cell transplant

AND

4 - The patient will be treated with the recommended dose of 1 x 106 CAR-positive viable T cells per kg (kilogram) body weight, with a maximum of 1 x 108 CAR-positive viable T cells

AND

5 - The patient has received or will receive a lymphodepleting chemotherapy regimen of fludarabine 25 mg/m^2 intravenously on the preceding fourth, third and second days before infusion of Tecartus

AND

6 - The patient has received or will receive a lymphodepleting chemotherapy regimen of cyclophosphamide 900 mg/m^2 on the second day before infusion of Tecartus

AND

7 - The patient has not received prior treatment with CAR T-cell therapy

AND

8 - If the patient has had a prior allogeneic HSCT, the patient does not currently have active GVHD

2 . Revision History

Date	Notes
7/12/2023	Updated all criteria, cleaned up criteria language.

Tegsedi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-78549
Guideline Name	Tegsedi
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	2/1/2021

1 . Criteria

Product Name: Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy

- Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Patient has not had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

Product Name: Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received treatment with Tegsedi

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient continues to have a neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Documentation that the patient has experienced a positive clinical response to Tegsedi therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

5 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

2 . Revision History

Date	Notes
12/17/2020	Added examples of tafamidis products but no change to clinical inten t.

Test Strips

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127187
Guideline Name	Test Strips
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Non-preferred Test Strips	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure of both of the following confirmed by claims history or submitted medical records:

- OneTouch Ultra Test Strips
- OneTouch Verio Test Strips

OR

1.2 History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- OneTouch Ultra Test Strips
- OneTouch Verio Test Strips

OR

2 - Patient is on an insulin pump

Product Name: All Test Strips	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - If the patient is insulin dependent or pregnant, the physician must confirm the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)

OR

2 - If the patient is not insulin dependent nor pregnant, ONE the following:

2.1 The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control

OR

2.2 The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time

OR **2.3** The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time **OR** **2.4** The patient requires additional testing due to fluctuations in blood glucose due to physical activity/exercise **OR** **2.5** Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by UnitedHealthcare reviewing pharmacist and/or medical director)

Notes	The quantity limit for insulin-dependent and pregnant patients is 6 test strips/day. The quantity limit for non-insulin dependent and non-pregnant patients is 2 test strips/day.

2 . Revision History

Date	Notes
6/27/2023	Added new GPIs to market since last update. No changes to clinical criteria.

Testosterone

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116670
Guideline Name	Testosterone
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Brand Androgel, generic testosterone gel 1% and 1.62%, Brand Testim, Brand Vogelxo, testosterone enanthate, Androderm, testosterone soln, testosterone cypionate, Tlando, Jatenzo, Kyzatrex	
Diagnosis	Hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 TWO pre-treatment serum total testosterone levels less than 300 ng/dL

(nanograms/deciliter) [less than 10.4 nmol/L (nanomoles/liter)] or less than the reference range for the lab, taken at separate times (document lab value and date for both levels)

OR

1.2 BOTH of the following:

1.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) [e.g., thyroid disorder, HIV (human immunodeficiency virus) disease, liver disorder, diabetes, obesity]

AND

1.2.2 ONE pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (picograms/milliliter) (less than 5 ng/dL or less than 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

OR

1.3 Patient has a history of ONE of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

AND

2 - Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

3 - Patient is NOT taking with an aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

AND

4 - Patient was male at birth

AND

5 - Diagnosis of hypogonadism

AND

6 - ONE of the following:

- Significant reduction in weight (less than 90 percent ideal body weight) [e.g., AIDS (acquired immunodeficiency syndrome) wasting syndrome]
- Osteopenia
- Osteoporosis
- Decreased bone density
- Decreased libido
- Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

AND

7 - If the request is for generic Androgel, patient must have tried and failed Brand Androgel (verified via paid pharmacy claims or submission of medical records)

AND

8 - If the request is for Jatenzo, Kyzatrex, or Tlando, patient must have tried and failed Brand Androgel or Androderm (verified via paid pharmacy claims or submission of medical records)

Product Name: Brand Androgel, generic testosterone gel 1% and 1.62%, Brand Testim, Brand Vogelxo, testosterone enanthate, Androderm, testosterone soln, testosterone cypionate, Tlando, Jatenzo, Kyzatrex	
Diagnosis	Gender Dysphoria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is using hormones to change physical characteristics

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

AND

3 - Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

4 - Patient is NOT taking with an aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

AND

5 - If the request is for generic Androgel, patient must have tried and failed Brand Androgel (verified via paid pharmacy claims or submission of medical records)

AND

6 - If the request is for Jatenzo, Kyzatrex, or Tlando, patient must have tried and failed Brand Androgel or Androderm (verified via paid pharmacy claims or submission of medical records)

Product Name: Brand Androgel, generic testosterone gel 1% and 1.62%, Brand Testim, Brand Vogelxo, testosterone enanthate, Androderm, testosterone soln, testosterone cypionate, Tlando, Jatenzo, Kyzatrex	
Diagnosis	Hypogonadism, Gender Dysphoria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

OR

1.2 Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

OR

1.3 BOTH of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG)

[e.g., thyroid disorder, HIV (human immunodeficiency virus) disease, liver disorder, diabetes, obesity]

AND

1.3.2 ONE of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

AND

2 - Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

3 - Patient is NOT taking with an aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

2 . Revision History

Date	Notes

11/7/2022	Added Kyzatrex as NP target.

Thalomid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110732
Guideline Name	Thalomid
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	

Product Name: Thalomid	
Diagnosis	Multiple Myeloma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL)

AND

2 - ONE of the following:

2.1 Used for acute treatment

OR

2.2 Used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Aphthous Stomatitis or Ulcer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, recurrent aphthous stomatitis or ulcer

Product Name: Thalomid	
Diagnosis	Aphthous Stomatitis or Ulcer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Pyoderma Gangrenosum
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pyoderma gangrenosum

AND

2 - Used as third line treatment

Product Name: Thalomid	
Diagnosis	Pyoderma Gangrenosum
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Cutaneous Manifestations Systemic Lupus Erythematosus (SLE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous manifestations of systemic lupus erythematosus (SLE)

Product Name: Thalomid	
Diagnosis	Cutaneous Manifestations Systemic Lupus Erythematosus (SLE)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Castleman's Disease (CD)

AND

2 - NOT used as first line therapy

Product Name: Thalomid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary myelofibrosis

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Serum erythropoietin levels less than 500 mU/mL

AND

2.1.2 History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]

OR

2.2 Serum erythropoietin levels greater than or equal to 500 mU/mL

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that member has evidence of symptom improvement or reduction in spleen-liver volume while on Thalomid

Product Name: Thalomid	
Diagnosis	Acquired Immunodeficiency Syndrome (AIDS)- Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Acquired Immunodeficiency Syndrome (AIDS)- Related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - Not used as first line therapy

Product Name: Thalomid	
Diagnosis	AIDS- Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Thalomid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Therapeutic Duplication (Subtype A)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135037
Guideline Name	Therapeutic Duplication (Subtype A)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/17/2023

1 . Criteria

Product Name: Generic arformoterol nebulizer solution, Brand Brovana nebulizer, generic formoterol nebulizer solution, Brand Perforomist nebulizer, Striverdi Respimat, Serevent Diskus, Incruse Ellipta, Brand Spiriva Handihaler, generic tiotropium, Spiriva Respimat, Tudorza Pressair, generic ipratropium inhalation solution, Atrovent HFA, Anoro Ellipta, Stiolto Respimat, Bevespi Aerosphere, Duaklir Pressair, Breztri Aerosphere, Glyxambi, Steglujan, Qtern, Trijardy XR, Brand Pulmicort suspension, generic budesonide suspension, Victoza, Adlyxin, Trulicity, Bydureon BCise, Byetta, Ozempic, Rybelsus, Januvia, Janumet, Janumet XR, Brand Onglyza, generic saxagliptin, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Tradjenta, Jentadueto, Jentadueto XR, Nesina, alogliptin, Kazano, alogliptin/metformin, Oseni, alogliptin/pioglitazone, Mounjaro, Xultophy, Soliqua, Invokana, Farxiga, Jardiance, Invokamet, Invokamet XR, Xigduo XR, Synjardy, Synjardy XR, Steglatro, Segluromet, Brand Flovent HFA, Brand Fluticasone propionate HFA, Flovent Diskus, Brand Pulmicort Flexhaler, Airsupra, Alvesco, ArmonAir Digihaler, Asmanex Twisthaler, Asmanex HFA, Arnuity Ellipta, Qvar RediHaler, Lonhala Magnair, Trelegy Ellipta, Brand Advair Diskus, generic fluticasone propionate/salmeterol diskus (generic Advair Diskus), generic Wixela Inhub (generic Advair Diskus), AirDuo Respiclick, fluticasone/salmeterol (authorized generic of AirDuo), Brand Advair HFA, Brand Fluticasone/salmeterol HFA, Brand Symbicort, generic budesonide/formoterol, Breyna, AirDuo Digihaler, Dulera, Breo Ellipta, Brand

fluticasone/vilanterol Ellipta, Basaglar Tempo pen, Basaglar Kwikpen, Insulin Glargine Solostar, Lantus Solostar, Toujeo Solostar, Toujeo Max Solostar, Semglee Pen Injector, Insulin Glargine-YFGN pen, Lantus vial, Insulin Glargine vial, Semglee vial, Insulin Glargine-YFGN vial, Levemir vial, Levemir Flextouch, Levemir Flexpen, Tresiba vial, Insulin Degludec vial, Tresiba Flextouch, Insulin Degludec Flextouch, Rezvoglar, Baclofen tabs, generic baclofen suspension, Brand Fleqsuvy, Ozobax DS, brand Ozobax, Brand Baclofen solution, brand Lioresal intrathecal, generic baclofen intrathecal, brand Gablofen intrathecal, baclofen intrathecal solution, Lyvispah, generic carisoprodol tab, brand Soma, brand Vanadom tab, generic chlorzoxazone, brand Lorzone, generic cyclobenzaprine, brand Fexmid, generic cyclobenzaprine ER, brand Amrix, metaxalone, methocarbamol, orphenadrine CR/ER, generic tizanidine caps/tabs, brand Zanaflex caps/tabs, brand Dantrium, generic dantrolene, brand Norgesic, generic orphenadrine/aspirin/caffeine, norgesic forte, orphengesic forte, Brand Neurontin caps/tabs/soln, generic gabapentin caps/tabs/soln, gabapentin tinytabs, brand Lyrica caps/soln, generic pregabalin caps/soln, brand Gralise, brand Lyrica CR, generic pregabalin ER, Horizant, Zorvolex, brand Zipsor, generic diclofenac caps, brand Lofena, generic diclofenac tabs, diclofenac DR/ER, brand Cambia, generic diclofenac packet (migraine), etodolac cap, brand Lodine, generic etodolac tab, etodolac ER, brand Nalfon caps/tabs, generic fenoprofen caps/tabs, flurbiprofen, ibuprofen caps/tabs/chewable (includes All Manufactures), Brand Advil, ibuprofen suspension (40 mg/ml & 100 mg/5ml), indomethacin caps, indomethacin ER/SR caps, indocin susp, indocin suppository, indomethacin suppository, ketoprofen cap, ketoprofen ER cap, ketorolac tabs, meclofenamate cap, mefenamic acid, meloxicam cap/tab, brand Relafen DS, generic nabumetone, generic naproxen tab/susp/caps (includes All Manufactures), brand naprosyn tab/susp, brand Aleve, brand Anaprox DS, brand EC-Naprosyn, generic naproxen DR, generic EC-naproxen, brand Naprelan, generic naproxen CR/ER, Brand Daypro, generic oxaprozin, brand Feldene, generic piroxicam, sulindac, tolmetin, brand Celebrex, generic celecoxib, Elyxyb, brand Arthrotec, generic diclofenac sodium/misoprostol, brand Duexis, generic ibuprofen/famotidine, brand Vimovo, generic naproxen/esomeprazole, brand Advil PM, generic ibuprofen/diphenhydramine, brand Aleve PM, generic naproxen/diphenhydramine, hydrocodone/ibuprofen, brand Treximet, generic sumatriptan/naproxen, Motrin Dual Action/Tylenol, Advil Dual Action/acetaminophen, Naproxen/capsaicin cream (Naprotin), Inpefa, Saxenda, Wegovy, Brenzavvy

Diagnosis	DUR: Therapeutic Duplication
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication will be used exclusively, and the previously prescribed medication will be discontinued

OR

2 - All of the following:

2.1 The requested medication combination is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2.2 The drug combination is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

AND

2.3 The provider attests that they are aware that the patient is using duplicate therapy

AND

2.4 Special clinical circumstances exist that necessitate the need for duplicate therapy (document special circumstances)

AND

2.5 Provider attests that the necessity for continued concomitant therapy and safety will be periodically assessed

2 . Revision History

Date	Notes
11/16/2023	Added new Breo GPI and Airsupra. Updated other current GPIs and product names due to new market availability of products (brands, ge nerics, authorized generics; etc).

Therapeutic Duplication (Subtype B)

Prior Authorization Guideline

Guideline ID	GL-135382
Guideline Name	Therapeutic Duplication (Subtype B)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/17/2023

1 . Criteria

Product Name: (All formulations/packaging, except for Enyvio) Entyvio Pen, Stelara, Cimzia, Abrilada, Humira, Amjevita, Idacio, Hulio, Cyltezo, Yusimry, Yuflyma, Hadlima, Hyrimoz, adalimumab, Simponi, Enbrel, Actemra, Cosentyx, Ilaris, Kineret, Kevzara, Taltz, Tremfya, Orencia, Xeljanz, Xeljanz XR, Xeljanz Solution, Siliq, Otezla, Olumiant, Ilumya, Skyrizi, Rinvoq, Sotyktu, Cibinqo, Adbry, Dupixent, brand Copaxone, generic glatiramer acetate, generic glatopa, Mavenclad, Rebif, Avonex, Betaseron, Extavia, brand Aubagio, generic teriflunomide, Plegridy, Lemtrada, Tysabri, Ocrevus, brand Tecfidera, generic dimethyl fumarate, Vumerity, brand Gilenya, generic fingolimod, Tascenso ODT, Zeposia, Mayzent, Bafiertam, Kesimpta, Ponvory, Xolair, Fasenra, Nucala, Cinqair, Tezspire, Velsipity, Bimzelx, Omvoh	
Diagnosis	DUR: Therapeutic Duplication
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - The requested medication will be used exclusively, and the previously prescribed medication will be discontinued

2 . Revision History

Date	Notes
11/16/2023	Updated Tecfidera (dimethyl fumarate) and Cosentyx GPI. Added ne w Hyrimoz and adalimumab-abdm GPIs. Added Abrilada, Entyvio pe n, Velspity, Bimzelx and Omvoh GPI and updated product names.

Thrombopoiesis Stimulating Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121090
Guideline Name	Thrombopoiesis Stimulating Agents
Formulary	• Medicaid - Community & State Arizona • Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Nplate, Promacta tablet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic immune thrombocytopenia (ITP)	

AND

2 - History of failure, contraindication, or intolerance to ONE of the following:

- Corticosteroids
- Immunoglobulins
- Splenectomy

Notes	*Note: Drugs may require PA

Product Name: Doptelet, Promacta powder pack/oral suspension, Tavalisse	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of failure, contraindication, or intolerance to ONE of the following:

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

2.1.2 History of failure, contraindication, or intolerance to BOTH of the following preferred alternatives*:

- Promacta Tablet (eltrombopag)*
- Nplate (romiplostim)*

OR

2.2 Patient is currently stable on requested non-preferred medication

Notes	*Note: Drugs may require PA

Product Name: Doptelet, Nplate, Promacta tablets, Promacta powder pack/oral suspension, Tavalisse	
Diagnosis	Chronic Immune (idiopathic) thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Promacta tablets, Promacta powder pack/oral suspension	
Diagnosis	Severe Aplastic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - One of the following:

2.1 Used in combination with standard immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

OR

2.2 History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

AND

3 - For Promacta powder pack/oral suspension ONLY: clinical rationale for use instead of preferred Promacta tablet

Product Name: Promacta tablets, Promacta powder pack/oral suspension	
Diagnosis	Severe Aplastic Anemia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Promacta tablet	
Diagnosis	Chronic Hepatitis C-associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic Hepatitis C-associated thrombocytopenia

AND

2 - One of the following:

- Planning to initiate and maintain interferon-based treatment
- Currently receiving interferon-based treatment

Product Name: Promacta tablet	
Diagnosis	Chronic Hepatitis C-associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is currently on antiviral interferon therapy for treatment of chronic Hepatitis C

Product Name: Doptelet, Mulpleta	
Diagnosis	Thrombocytopenia
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thrombocytopenia

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - History of failure, contraindication, or intolerance to BOTH of the following preferred alternatives*:

- Promacta Tablets (eltrombopag)*
- Nplate (romiplostim)*

Notes	*Note: Drugs may require PA

Product Name: Nplate	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]

AND

2 - Patient is receiving myelosuppressive doses of radiation

2 . Revision History

Date	Notes
2/8/2023	New

Tobramycin Inhalation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82382
Guideline Name	Tobramycin Inhalation
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2021

1 . Criteria

Product Name: Brand Bethkis, Kitabis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

Product Name: Brand TOBI Nebulizer Solution, generic tobramycin solution for inhalation, TOBI Podhaler	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Lung infection with positive culture demonstrating Pseudomonas aeruginosa infection

AND

3 - History of failure, intolerance, or contraindication to BOTH of the following

- Brand Bethkis
- Kitabis

Product Name: Brand TOBI Nebulizer Solution, generic tobramycin solution for inhalation, TOBI Podhaler	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/10/2021	Added generic Bethkis. Updated product name listing of first criteria box to specify brand Bethkis and updated NP language to specify T/F must be brand Bethkis.

Topical Capsaicin Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137467
Guideline Name	Topical Capsaicin Products
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Diclareal	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of osteoarthritis of the knees

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting history of failure to ALL of the following:

- diclofenac 1% topical gel
- diclofenac 2% topical solution
- topical capsaicin cream/patch

Product Name: Trubrexa	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming requested medication is being used for the treatment of acute and chronic pain in muscles and joints associated with muscle soreness, strains, sprains, arthritis, simple backache, muscle stiffness, etc.

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial and failure, contraindication, or intolerance to ALL of the following:

- diclofenac 1% topical gel
- topical capsaicin cream/patch
- topical lidocaine patch

2 . Revision History

Date	Notes
12/7/2023	New guideline

Topical NSAIDs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110367
Guideline Name	Topical NSAIDs
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Flector Patch, generic diclofenac epolamine 1.3% patch	
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute pain due to minor strains, sprains, or contusions

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)
- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI (gastrointestinal) bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

Product Name: Pennsaid 2%, diclofenac sodium soln 1.5%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of pain due to osteoarthritis of the knee(s)

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)
- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis

- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

AND

3 - Patient has a history of failure, intolerance, or contraindication to diclofenac topical gel 1% (Rx formulation), or Voltaren OTC (over the counter)

Product Name: generic diclofenac topical gel 1% (Rx formulation), Voltaren OTC	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of pain due to osteoarthritis of joints amenable to topical treatment, including but not limited to the hands, knees, ankles, elbows, feet, and wrists

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)

- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Trelegy Ellipta

Prior Authorization Guideline

Guideline ID	GL-121161
Guideline Name	Trelegy Ellipta
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name: Trelegy Ellipta	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Brand Symbicort

Product Name: Trelegy Ellipta	
Diagnosis	COPD
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema

AND

2 - History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of BOTH of the following used in combination:

- Stiolto Respimat (tiotropium-olodaterol)
- Flovent HFA (fluticasone propionate)

Product Name: Trelegy Ellipta	
Diagnosis	Asthma, COPD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
2/9/2023	Removed TD criteria section.

Tremfya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110688
Guideline Name	Tremfya
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 BOTH of the following:

1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.5 Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.6 Prescribed by or in consultation with a dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

AND

2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

2.3 Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

AND

1.3 History of failure, contraindication, or intolerance to THREE of the following preferred biologic products (document drug, date, and duration of trial):

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.4 Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.5 Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Tretinoin Capsules

Prior Authorization Guideline

Guideline ID	GL-110327
Guideline Name	Tretinoin Capsules
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Tretinoin capsules	
Diagnosis	Acute Promyelocytic Leukemia (APL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acute promyelocytic leukemia	

Product Name: Tretinoin capsules	
Diagnosis	Acute Promyelocytic Leukemia (APL)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tretinoin capsules

Product Name: Tretinoin capsules	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tretinoin capsules will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tretinoin capsules	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tretinoin capsules

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Tretinoin Topical

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110377
Guideline Name	Tretinoin Topical
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Retin-A cream and gel*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 26 years of age or less

OR

1.2 Both of the following:

- Patient is greater than 26 years of age
- Diagnosis of acne vulgaris

AND

2 - The patient must have a history of therapeutic failure, contraindication, or intolerance to ALL of the following:

- benzoyl peroxide
- topical clindamycin
- topical erythromycin

Notes	*Only Brand Covered

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Trikafta (elexacaftor/tezacaftor/ivacaftor)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126432
Guideline Name	Trikafta (elexacaftor/tezacaftor/ivacaftor)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Trikafta (80-40-60 mg) granules packet, Trikafta (100-50-75 mg) granules packet	
Diagnosis	Cystic Fibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

AND

2 - Submission of laboratory results documenting that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data

AND

3 - Patient is between 2 and 6 years of age

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Trikafta (50-25-37.5 mg) tablet pack, Trikafta (100-50-75 mg) tablet pack	
Diagnosis	Cystic Fibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results documenting that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data

AND

3 - The patient is 6 years of age or older

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Trikafta granules packets, Trikafta tablet packs	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Trikafta therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Revision History

Date	Notes
6/8/2023	Added criteria for granule packets. Updated GL name

Triptans

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110349
Guideline Name	Triptans
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Amerge, generic sumatriptan nasal spray, brand Imitrex tablets, Brand Imitrex injection, generic sumatriptan 6mg PFS, generic almotriptan, brand Maxalt, brand Maxalt MLT, Onzetra Xsail, brand Relpax, generic eletriptan, brand Treximet, generic sumatriptan naproxen, Zembrace, brand Zomig, brand Zomig ZMT, brand Frova, generic frovatriptan, Tosymra	
Diagnosis	Non-preferred products
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of migraine headaches with or without aura	

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least three preferred products (document drugs, duration, and date of trials)*

- brand Imitex Nasal Spray
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt)
- sumatriptan (Generic Imitrex)
- zolmitriptan (Generic Zomig)

Product Name: Brand Imitrex (inj, cartridge, auto-injector and PFS), generic sumatriptan (inj, cartridge, auto-injector and PFS)*	
Diagnosis	Migraine Headaches with or without Aura
Approval Length	12 month(s)
Guideline Type	Quantity Limits

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient is currently receiving prophylactic therapy with at least ONE of the following:

3.1 Amitriptyline (Elavil)

OR

3.2 One of the following beta-blockers:

- atenolol
- metoprolol
- nadolol**
- propranolol
- timolol**

OR

3.3 Divalproex sodium (Depakote/Depakote ER)

OR

3.4 OnabotulinumtoxinA (Botox) ***

OR

3.5 Topiramate (Topamax)

OR

3.6 Venlafaxine (Effexor/Effexor XR)

OR

3.7 Calcitonin gene-related peptide (CGRP) receptor antagonists [e.g., Aimovig (erenumab), Emgality (galcanezumab)]

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See "Quantity Limits" table in background section for quantity limits ** Nadolol and timolol are non-preferred and should not be included in denial to provider *** OnabotulinumtoxinA (Botox) is a medical benefit, should not be inc luded in denial to provider

Product Name: Brand Imitrex (inj, cartridge, auto-injector and PFS), generic sumatriptan (inj, cartridge, auto-injector and PFS)*	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of cluster headaches

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See “Quantity Limits” table in background section for quantity limits

Product Name: Brand Amerge, generic naratriptan, Brand Frova, generic frovatriptan, Brand Imitrex tablets and nasal spray, generic sumatriptan tablets and nasal spray, generic almotriptan, Brand Maxalt and Maxalt MLT, generic rizatriptan and rizatriptan MLT, Onzetra Xsail, Brand Relpax, generic eletriptan, Brand Treximet, generic sumatriptan-naproxen, Zembrace Sym Touch, Brand Zomig and Zomig ZMT, generic zolmitriptan and zolmitriptan ZMT, brand Zomig nasal, generic zolmitriptan nasal spray, Tosymra *	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient is currently receiving prophylactic therapy with at least ONE of the following:

3.1 Amitriptyline (Elavil)

OR

3.2 One of the following beta-blockers:

- atenolol
- metoprolol
- nadolol**
- propranolol
- timolol**

OR

3.3 Divalproex sodium (Depakote/Depakote ER)

OR

3.4 OnabotulinumtoxinA (Botox) ***

OR

3.5 Topiramate (Topamax)

OR

3.6 Venlafaxine (Effexor/Effexor XR)

OR

3.7 Calcitonin gene-related peptide (CGRP) receptor antagonists [e.g., Aimovig (erenumab), Emgality (galcanezumab)]

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA (Food and Drug Administration) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See “Quantity Limits” table in background section for quantity limits ** Nadolol and timolol are non-preferred and should not be included in denial to provider *** OnabotulinumtoxinA (Botox) is a medical benefit, should not be inc luded in denial to provider

Product Name: Brand Zomig nasal spray, generic zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient has a history of failure, contraindication, or intolerance to a trial of Imitrex Nasal Spray

AND

2 - If the request is for generic zolmitriptan nasal spray, patient must have tried and failed Brand Zomig Spray

2 . Background

Benefit/Coverage/Program Information

Quantity Limits

Quantity Limits

Drug Name	Strength	Quantity Limit
Brand Amerge generic naratriptan	1mg, 2.5mg	9 tabs/month
Brand Frova Generic frovatriptan	2.5mg	9 tabs/month
Brand Imitrex tablets generic sumatriptan tablets	25mg, 50mg, 100mg	9 tabs/month
Brand Maxalt Generic rizatriptan	5mg, 10mg	9 tabs/month
Brand Maxalt MLT Generic rizatriptan ODT	5mg, 10mg	9 tabs/month
Generic almotriptan	6.25mg, 12.5mg	6 tabs/month
Relpax Generic eletriptan	20mg, 40mg	6 tabs/month
Brand Zomig Generic zolmitriptan	2.5mg, 5mg	6 tabs/month

Brand Zomig ZMT Generic zolmitriptan ODT	2.5mg, 5mg	6 tabs/month
Brand Imitrex Nasal Spray Generic sumatriptan nasal spray	5mg, 20mg	6 spray devices/month
Zomig Nasal Spray	2.5mg, 5mg	6 spray devices/month
Treximet Generic sumatriptan/naproxen	85mg/500 mg, 10mg/60mg	9 tabs/month
Onzetra Xsail	11mg	1 box (8 units)/month
Zembrace SymTouch	3mg	1 box (4 units)/month
Brand Imitrex Generic Sumatriptan Autoinjector/Cartridge Refills	4mg/0.5mL 6mg/0.5mL	8 autoinjectors or cartridge refills/month (4 boxes/month)
Brand Imitrex Generic Sumatriptan Vials	6mg/0.5mL	10 vials/month (2 boxes/month)
Generic Sumatriptan Pre-filled Syringe	6mg/0.5mL	8 prefilled syringes (4 boxes/month)
Tosymra nasal spray	10mg	6 units per month

3 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Twyneo (tretinoin-benzoyl peroxide 0.1-3% cream)

Prior Authorization Guideline

Guideline ID	GL-110296
Guideline Name	Twyneo (tretinoin-benzoyl peroxide 0.1-3% cream)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Twyneo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Both of the following:

- Patient is 9 years of age or older
- Diagnosis of acne vulgaris

AND

1.2 The patient must have a history of therapeutic failure, contraindication, or intolerance to ALL of the following (verified via paid pharmacy claims or submission of medical records):

- benzoyl peroxide
- topical clindamycin
- topical erythromycin
- topical tretinoin (Brand Retin-A)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Uloric

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64416
Guideline Name	Uloric
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Brand Uloric, generic febuxostat	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication or intolerance to allopurinol (generic Zyloprim)	

2 . Revision History

Date	Notes

3/31/2020	Bulk Copy C&S New York to C&S Arizona for effective date of 5/1

Ultomiris (ravulizumab-cwvz)

Prior Authorization Guideline

Guideline ID	GL-115955
Guideline Name	Ultomiris (ravulizumab-cwvz)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is one month of age or older

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS)

AND

2 - Patient is one month of age or older

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two preferred immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one preferred immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/21/2022	New Program

Upneeq

Prior Authorization Guideline

Guideline ID	GL-80094
Guideline Name	Upneeq
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/1/2021

1 . Criteria

Product Name: Upneeq	
Diagnosis	Acquired Blepharoptosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired blepharoptosis

AND

2 - Patient has a functional impairment related to the position of the eyelid

AND

3 - ONE of the following:

3.1 Marginal reflex distance-1 (MRD-1) is less than or equal to 2 millimeters (mm) in primary gaze

OR

3.2 Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze

OR

3.3 Superior visual field loss of at least 12 degrees or 24 percent

AND

4 - Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injections, myasthenia gravis)

Product Name: Upneeq	
Diagnosis	Acquired Blepharoptosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

2 . Revision History

Date	Notes
1/26/2021	Copy of NY-79983 New Program

Urea Cycle Disorder Agents

Prior Authorization Guideline

Guideline ID	GL-129574
Guideline Name	Urea Cycle Disorder Agents
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Brand Buphenyl, generic sodium phenylbutyrate, Pheburane	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 ONE of the following deficiencies:

- carbamylphosphate synthetase (CPS)
- ornithine transcarbamylase (OTC)
- argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene

AND

3 - If the request is for Brand Buphenyl or Pheburane, trial and failure, or intolerance to generic sodium phenylbutyrate

AND

4 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

5 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name: Olpruva, Ravicti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 ONE of the following deficiencies:

- carbamylphosphate synthetase (CPS)
- ornithine transcarbamylase (OTC)
- argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene

AND

3 - Inadequate response to ONE of the following:

- Dietary protein restriction
- Amino acid supplementation

AND

4 - Trial and failure, contraindication, or intolerance to generic sodium phenylbutyrate

AND

5 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

6 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name: Brand Buphenyl, generic sodium phenylbutyrate, Olpruva, Pheburane, Ravicti

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., plasma ammonia and amino acid levels within normal limits)

AND

2 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

2 . Revision History

Date	Notes
8/8/2023	Added Olpruva

Valchlor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110656
Guideline Name	Valchlor
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Chronic or smoldering T-cell leukemia-lymphoma
- Primary cutaneous marginal zone or follicle center B-cell lymphoma
- Lymphomatoid papulosis (LyP) with extensive lesions

- Mycosis fungoides (MF)-Sezary syndrome (SS)

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Valchlor will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Valchlor therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Valsartan oral solution

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115895
Guideline Name	Valsartan oral solution
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Valsartan oral solution	
Diagnosis	Patients 7 years of age or older
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 7 years of age or older

AND

2 - Patient cannot take solid dosage forms due to swallowing issues

2 . Revision History

Date	Notes
10/21/2022	New guideline

Vancomycin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110338
Guideline Name	Vancomycin
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	10 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]

AND **2** - If the request is for vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq and vancomycin capsules*

Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vanco mycin capsules are preferred.

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	12 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of Clostridioides difficile infection [previously known as Clostridium difficile-associated diarrhea] after prior treatment with oral vancomycin

Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vanco mycin capsules are preferred.

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Staphylococcus aureus
Approval Length	10 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Enterocolitis due to Staphylococcus aureus

AND **2** - If the request is for vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq and vancomycin capsules*	
Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vanco mycin capsules are preferred.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Vecamyl

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64556
Guideline Name	Vecamyl
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately severe to severe essential hypertension

OR

2 - Diagnosis of uncomplicated malignant hypertension

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Vecamyl therapy

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Velphoro (sucroferric oxyhydroxide), Auryxia (ferric citrate)

Prior Authorization Guideline

Guideline ID	GL-116675
Guideline Name	Velphoro (sucroferric oxyhydroxide), Auryxia (ferric citrate)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Velphoro, Auryxia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following

- Diagnosis of hyperphosphatemia
- Diagnosis of End Stage Renal Disease

AND

2 - Adherence to and trial and failure to ONE of the following at maxiumum dosages (MUST be verified via paid pharmacy claims or submission of medical records) • Sevelamer Carbonate at the maximum dosage – 800mg/15 per day • Sevelamer Powder Packets at maximum dosage – 2.4gm packet 4 per day	
Notes	1. Approval will not be granted for requests based on potential side effects, i.e., constipation 2. Approval will not be granted for submitted prior authorizations based on pill burden. Velphoro and Sevelamer are both taken 3 times a day.

2 . Revision History

Date	Notes
11/7/2022	Removed Fosrenol as prerequisite option

Veltassa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116096
Guideline Name	Veltassa
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Veltassa	
Diagnosis	Non-Life Threatening Hyperkalemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-life threatening hyperkalemia

AND

2 - Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-steroidal anti-inflammatory drugs [NSAIDs]) have been discontinued or reduced to the lowest effective dose

AND

3 - Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

AND

4 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

AND

5 - History of failure, intolerance, or contraindication to Lokelma

Product Name: Veltassa	
Diagnosis	Non-Life Threatening Hyperkalemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a positive clinical response to Veltassa therapy

AND

2 - Patient continues to require treatment for hyperkalemia

AND **3** - Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-steroidal anti-inflammatory drugs [NSAIDs])) have been discontinued or reduced to the lowest effective dose

2 . Revision History

Date	Notes
10/28/2022	Added step through preferred Lokelma .

Vemlidy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118264
Guideline Name	Vemlidy
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Vemlidy	
Diagnosis	Treatment-Naïve Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a contraindication to entecavir therapy

AND

2 - Patient is 12 years of age or older

Product Name: Vemlidy	
Diagnosis	Treatment-Experienced Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient is currently on Viread therapy

AND

1.2 ONE of the following:

- Patient has a creatinine clearance less than 60 mL (milliliters) per minute
- Patient has a diagnosis of osteoporosis

AND

1.3 Patient is 12 years of age or older

OR

2 - Patient is currently on Vemlidy therapy

2 . Revision History

Date	Notes
12/13/2022	Updated guideline type in criteria, added age requirement in criteria.

Veozah (fezolinetant)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129692
Guideline Name	Veozah (fezolinetant)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Veozah	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial

and failure, contraindication, or intolerance to BOTH of the following (document drug, date, and duration of trial): • Menopausal hormone therapy (e.g., Premarin, Bijuva, Estrogel, etc.) • Non-hormonal therapy (e.g., paroxetine mesylate, venlafaxine, clonidine, etc.)

Product Name: Veozah	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy (e.g., decrease in frequency and severity of vasomotor symptoms from baseline, etc.)	

2 . Revision History

Date	Notes
8/10/2023	New guideline

Verkazia (cyclosporine ophthalmic emulsion 0.1%)

Prior Authorization Guideline

Guideline ID	GL-110295
Guideline Name	Verkazia (cyclosporine ophthalmic emulsion 0.1%)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Verkazia	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia)

AND

1.2 Trial and failure, contraindication, or intolerance to one of the following (verified via pharmacy paid claims or submission of medical records):

- Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine)
- Topical ophthalmic mast cell stabilizers (e.g., cromolyn)

AND

1.3 Trial and failure, contraindication, or intolerance, for short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone) ((verified via pharmacy paid claims or submission of medical records)

AND

2 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

Product Name: Verkazia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Verquvo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118513
Guideline Name	Verquvo
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Verquvo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of heart failure

AND

2 - Ejection fraction is less than 45 percent

AND

3 - Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

AND

4 - ONE of the following:

4.1 Hospitalization for heart failure within the past six months

OR

4.2 Outpatient IV (intravenous) diuretics for heart failure within the past three months

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated beta-blocker (e.g., bisoprolol, carvedilol, metoprolol) confirmed by claims history or submission of medical records

OR

5.2 Patient has a contraindication or intolerance to beta-blocker therapy (please specify intolerance or contraindication)

AND

6 - ONE of the following:

6.1 Patient is on a stabilized dose and receiving concomitant therapy with one of the following confirmed by claims history or submission of medical records:

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Angiotensin II receptor blocker (ARB) (e.g., losartan)
- Angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto)

OR

6.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors, ARBs, and ARNIs (please specify intolerance or contraindication)

AND

7 - ONE of the following:

7.1 Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated aldosterone antagonist (e.g., spironolactone) confirmed by claims history or submission of medical records

OR

7.2 Patient has a contraindication or intolerance to aldosterone antagonist therapy (please specify intolerance or contraindication)

AND

8 - ONE of the following:

8.1 BOTH of the following:

8.1.1 Patient has an ejection fraction less than or equal to 40%

AND

8.1.2 ONE of the following:

8.1.2.1 Patient is on a stabilized dose and receiving concomitant therapy with a sodium-

glucose cotransporter 2 (SGLT2) inhibitor indicated for heart failure (e.g., Farxiga) confirmed by claims history or submission of medical records

OR

8.1.2.2 Patient has a contraindication or intolerance to SGLT2 inhibitor therapy (please specify intolerance or contraindication)

OR

8.2 Patient has an ejection fraction < 45% but > 40%

AND

9 - Verquvo is prescribed by or in consultation with a cardiologist

Product Name: Verquvo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Vijoice (alpelisib)

Prior Authorization Guideline

Guideline ID	GL-110602
Guideline Name	Vijoice (alpelisib)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Vijoice	
Approval Length	6 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - Submission of documentation of mutation in the PIK3CA gene

AND

3 - Patient is 2 years of age or older

AND

4 - Submission of documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])

AND

5 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

Product Name: Vijoice	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation of positive clinical response to therapy (e.g., radiological response defined as a ≥ 20% reduction from baseline in the sum of target lesion volume)

AND

2 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

2 . Revision History

Date	Notes

8/4/2022	C&S to match AZM as of 10.1.22

Viltepso

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-89709
Guideline Name	Viltepso
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2021

1 . Criteria

Product Name: Viltepso	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD) by, or in consultation with, a neurologist with expertise in the diagnosis of DMD

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 53 skipping

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Time (6MWT) greater than or equal to 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Viltepso therapy

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3.2.2 ONE of the following:

3.2.2.1 Patient has achieved a score of greater than 17 on the North Star Ambulatory Assessment (NSAA)

OR

3.2.2.2 Patient has achieved a time to rise from the floor (Gower's test) of less than 7 seconds

AND

4 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD

AND

5 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

6 - Not used concomitantly with other exon skipping therapies for DMD

Product Name: Viltepso	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD (Duchenne muscular dystrophy)

AND

2 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

4 - Not used concomitantly with other exon skipping therapies for DMD

2 . Revision History

Date	Notes
7/9/2021	New guideline, aligns with medical drug policy

Vivjoa (oteseconazole)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115896
Guideline Name	Vivjoa (oteseconazole)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Vivjoa	
Approval Length	4 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent vulvovaginal candidiasis (RVVC)

AND

2 - Patient is NOT of reproductive potential

AND

3 - Diagnosis of RVVC confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Vaginal fungal culture

AND

4 - Patient has experienced 3 or more symptomatic episodes of vulvovaginal candidiasis (VVC) within the past 12 months

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

- One intravaginal product (e.g., clotrimazole, miconazole, tioconazole, terconazole, boric acid)
- Oral fluconazole

2 . Revision History

Date	Notes
10/21/2022	New guideline

Vonjo (pacritinib)

Prior Authorization Guideline

Guideline ID	GL-110599
Guideline Name	Vonjo (pacritinib)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Vonjo	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of ONE of the following:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

1.2 Disease is intermediate or high risk

AND

1.3 Pre-treatment platelet count below 50 x 10^9 L

AND

2 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Oncologist

Product Name: Vonjo	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

Product Name: Vonjo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - This drug will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B	

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin), Voquezna Dual Pak (vonoprazan, amoxicillin)

Prior Authorization Guideline

Guideline ID	GL-115897
Guideline Name	Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin), Voquezna Dual Pak (vonoprazan, amoxicillin)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Voquezna Dual Pak, Voquezna Triple Pak	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Helicobacter pylori infection

AND

2 - Trial and failure, contraindication, or intolerance to BOTH of the following first line treatment regimens

- Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy)
- Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])

2 . Revision History

Date	Notes
10/24/2022	New guideline

Voxzogo (vosoritide)

Prior Authorization Guideline

Guideline ID	GL-137464
Guideline Name	Voxzogo (vosoritide)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Voxzogo	
Diagnosis	Achondroplasia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has open epiphyses

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of achondroplasia as confirmed by one of the following:

2.1 Both of the following:

2.1.1 Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

AND

2.1.2 Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

2.2 Molecular genetic testing confirmed c.1138G > A or c.1138G > C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

3 - Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Clinical geneticist
- Endocrinologist
- A physician who has specialized expertise in the management of achondroplasia

Notes	Requests for Idiopathic Short Stature (ISS) should not be approved. D eny as a benefit exclusion.

Product Name: Voxzogo	
Diagnosis	Achondroplasia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to have open epiphyses

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by one of the following:

- Improvement in annualized growth velocity (AGV) compared to baseline
- Improvement in height Z-score compared to baseline

AND

3 - Prescribed by or in consultation with one of the following:

- Clinical geneticist
- Endocrinologist
- A physician who has specialized expertise in the management of achondroplasia

Notes	Requests for Idiopathic Short Stature (ISS) should not be approved. Deny as a benefit exclusion.

2 . Revision History

Date	Notes
12/7/2023	Removed age criterion for Achondroplasia, removed ISS criteria section, added notes.

Vtama (tapinarof)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-115898
Guideline Name	Vtama (tapinarof)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Vtama	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting a diagnosis of plaque psoriasis

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting a minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies:

- Corticosteroids (e.g., betamethasone, clobetasol)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Vtama	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting positive clinical response to therapy as evidenced by one of the following:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

2 . Revision History

Date	Notes
10/21/2022	New guideline

Vuity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124445
Guideline Name	Vuity
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Vuity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of presbyopia

AND

2 - Patient is between the ages of 40 to 55

AND

3 - Patient is unable to use corrective lenses (e.g., glasses, contacts) (document medical rationale why patient is unable to use corrective lenses)

AND

4 - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

Product Name: Vuity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Age less than 55

AND

3 - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

Vyndaqel and Vyndamax

Prior Authorization Guideline

Guideline ID	GL-110761
Guideline Name	Vyndaqel and Vyndamax
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)	

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following

2.3.1 Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

AND

2.3.2 Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*

AND

2.3.3 Absence of monoclonal protein identified in serum, urine immunofixation (IFE), serum free light chain (sFLC) assay

AND

3 - Prescribed by, or in consultation, with a cardiologist

AND

4 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting presence of clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)

AND

5 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

5.1 ONE of the following:

5.1.1 Patient has New York Heart Association (NYHA) Functional Class I or II heart failure

OR

5.1.2 BOTH of the following:

5.1.2.1 Patient has New York Heart Association (NYHA) Functional Class III heart failure

AND

5.1.2.2 Patient's cardiopulmonary functional status allows patient to ambulate 100 meters or greater in six minutes or less

AND

5.2 Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to 600 picograms/milliliter

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) verifying patient is not receiving Vyndaqel or Vyndamax in combination with either of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

OR

6.2 If the patient is receiving Vyndaqel/Vyndamax in combination with Onpattro (patisiran) or Tegsedi (inotersen), the physician attests that he/she will coordinate care with other specialist(s) involved in the patient's amyloidosis treatment plan to determine optimal long term monotherapy** treatment regimen

Notes	NOTE: *May require prior authorization and notification ** Referring to monotherapy with Vyndaqel/Vyndamax, Onpattro, or T egsedi

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that the patient has experienced a positive clinical response to Vyndaqel or Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

AND

2 - Prescribed by or in consultation with a cardiologist

AND

3 - Submission of medical records (e.g., chart notes) documenting that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Paid claims or submission of medical records (e.g., chart notes) verifying patient is not receiving Vyndaqel or Vyndamax in combination with either of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Vyondys 53

Prior Authorization Guideline

Guideline ID	GL-105787
Guideline Name	Vyondys 53
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Vyondys 53	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Diagnosis of DMD by, or in consultation with, a neurologist with expertise in the diagnosis of DMD

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 53 skipping

AND

4 - One of the following

4.1 Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Time (6MWT) greater than or equal to 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Vyondys 53 therapy

OR

4.2 Both of the following:

4.2.1 Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

4.2.2 One of the following:

- Patient has achieved a score of greater than 17 on the North Star Ambulatory Assessment (NSAA)
- Patient has achieved a time to rise from the floor (Gower's test) of less than 7 seconds

Product Name: Vyondys 53	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of Duchenne muscular dystrophy (DMD)

AND

2 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3 - Serial monitoring of renal function (e.g., serum creatinine, proteinuria, serum cystatin C, 24-hour urine collection, etc.) has failed to identify evidence of renal toxicity with Vyondys 53

AND

4 - Vyondys 53 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling

AND

5 - Vyondys 53 is not used concomitantly with other exon skipping therapies for DMD

2 . Revision History

Date	Notes
4/7/2022	New guideline

Wakix

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110690
Guideline Name	Wakix
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Wakix	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a MSLT (Multiple Sleep Latency Test) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to the following: Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - One of the following:

3.1 Patient has a history of failure, contraindication, or intolerance to all of the following:

3.1.1 One of the following:

- An amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine)
- A methylphenidate-based stimulant

AND

3.1.2 Armodafinil (Nuvigil)

AND

3.1.3 Sunosi (solriamfetol)

OR

3.2 Patient has a history of or potential for a substance abuse disorder

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Wakix	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a reduction in symptoms of excessive daytime sleepiness associated with Wakix therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Welireg

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135115
Guideline Name	Welireg
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Welireg	
Diagnosis	Von Hippel-Lindau (VHL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Von Hippel-Lindau (VHL) disease

AND

2 - Patient requires therapy for one of the following:

- Renal cell carcinoma (RCC)
- Central nervous system (CNS) hemangioblastoma
- Pancreatic neuroendocrine tumor (pNET)

AND

3 - Patient does not require immediate surgery

Product Name: Welireg	
Diagnosis	Von Hippel-Lindau (VHL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of disease progression while on Welireg

Product Name: Welireg	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Welireg will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Welireg	
Diagnosis	NCCN Recommended Regimen

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Welireg therapy

2 . Revision History

Date	Notes
10/17/2023	Updated from standard to specialty formulary.

Xdemvy (lotilaner)

Prior Authorization Guideline

Guideline ID	GL-137473
Guideline Name	Xdemvy (lotilaner)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Xdemvy	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of Demodex blepharitis

AND

1.2 Patient exhibits one of the following signs of Demodex infestation:

- Collarettes
- Eyelid margin erythema
- Eyelash anomalies (e.g., eyelash misdirection)

AND

1.3 Patient is experiencing symptoms or architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward)

AND

1.4 Trial and inadequate response to tea tree-oil shampoo or eyelid scrub

AND

2 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

2 . Revision History

Date	Notes
12/7/2023	New guideline

Xeljanz, Xeljanz XR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116057
Guideline Name	Xeljanz, Xeljanz XR
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to all of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib) immediate-release tablets
- Orencia (abatacept)

AND

1.4 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) immediate-release
- Orencia (abatacept)

AND

1.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

1.2 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to Xeljanz (tofacitinib) immediate release tablets

AND

1.4 Prescribed by or in consultation with a gastroenterologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active UC

AND

2.3 Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication, or intolerance to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3.1.2 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib) immediate-release tablets

OR

3.2 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablet, Xeljanz XR	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by, or in consultation with, a rheumatologist

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication, or intolerance to one of the following nonbiologic DMARDs

- Leflunomide
- Methotrexate

AND

3.1.2 History of failure, contraindication, or intolerance to all of the following (applies to oral solution ONLY):

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib) immediate-release tablets
- Orencia (abatacept)

OR

3.2 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
10/25/2022	Updated criteria to match FFS. Removed criteria for concomitant therapy; added criteria for Ankylosing Spondylitis; Criteria and solution formulation added for dx of PJIA.

Xenazine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110628
Guideline Name	Xenazine
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chorea in patients with Huntington's disease	

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia (Off Label)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tardive dyskinesia

AND

2 - One of the following:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia (Off Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tourette's syndrome (off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome

AND

2 - History of failure, contraindication, or intolerance to Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tourette's syndrome (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Xenleta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110340
Guideline Name	Xenleta
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Xenleta	
Diagnosis	Community-acquired bacterial pneumonia
Approval Length	7 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 All of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta

AND

1.3.3 History of failure, contraindication, or intolerance to three of the following antibiotics:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name: Xenleta*	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR **1.2** As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **1.3** The medication is being prescribed by or in consultation with an infectious disease specialist	
Notes	*Approval Duration: Based on provider recommended treatment durations, not to exceed 6 months

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Xermelo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110629
Guideline Name	Xermelo
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoid syndrome diarrhea

AND

2 - Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)

AND

3 - Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xermelo

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Xofluza (baloxavir)

Prior Authorization Guideline

Guideline ID	GL-115899
Guideline Name	Xofluza (baloxavir)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Xofluza	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 5 years of age or older

AND

2 - ONE of the following:

- Patient has acute, uncomplicated influenza
- Used for post-exposure prophylaxis of influenza

AND

3 - Patient has not been symptomatic for more than 48 hours

AND

4 - Patient does NOT meet all of the following:

- On concurrent neuraminidase inhibitors (e.g., Tamiflu, Relenza)
- Pregnant
- Hospitalized

AND

5 - Documentation of reason why preferred generic oseltamivir is not clinically appropriate for the patient (i.e., the convenience of the patient, prescriber, or other health care provider should not be accepted)

2 . Revision History

Date	Notes
10/24/2022	New guideline

Xolair

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110630
Guideline Name	Xolair
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate or severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80 percent predicted [in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - ONE of the following:

3.1 Baseline (pre-omalizumab treatment) serum total Immunoglobulin E (IgE) level greater than or equal to 30 IU/mL (international units per milliliter) and less than or equal to 1500 IU/mL

OR

3.2 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

4 - Positive skin test or in vitro reactivity to a perennial aeroallergen

AND

5 - Used in combination with ONE of the following:

5.1 One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)-long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate-salmeterol (AirDuo, Advair), budesonide-formoterol (Symbicort)]

OR

5.2 Combination therapy including BOTH of the following:

5.2.1 One high-dose (appropriately adjusted for age) inhaled corticosteroid (ICS) product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

5.2.2 One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

6 - Patient is not receiving Xolair in combination with ONE of the following:

- Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

AND

7 - Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

AND

8 - Prescribed by or in consultation with an allergist-immunologist or pulmonologist

Product Name: Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by ONE of the following:

- reduction in frequency of exacerbations
- decreased utilization of rescue medications
- increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline
- reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing controller medication

AND

3 - Patient is not receiving Xolair in combination with ONE of the following:

- Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

AND

4 - Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

AND

5 - Prescribed by or in consultation with allergist-immunologist or pulmonologist

Product Name: Xolair	
Diagnosis	Chronic Idiopathic Urticaria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic urticaria

AND

2 - ONE of the following:

2.1 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]*

OR

2.2 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to BOTH of the following taken in combination:

2.2.1 Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

2.2.2 ONE of the following:

- Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
- First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*
- H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
- Leukotriene modifier [e.g., Singulair (montelukast)]

AND

3 - Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling

AND

4 - Prescribed by or in consultation with an allergist-immunologist or dermatologist

Notes	*Patients 65 years of age and older in whom first generation H1-antihi stamines are considered high risk medications to be avoided (e.g., Be ers criteria, HEDIS) should be directed to try alternatives that are not c onsidered high risk.

Product Name: Xolair	
Diagnosis	Chronic Idiopathic Urticaria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives)

AND **2** - Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling **AND** **3** - Prescribed by or in consultation with allergist-immunologist or dermatologist

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Xopenex Respules

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-80170
Guideline Name	Xopenex Respules
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	3/1/2021

1 . Criteria

Product Name: Brand Xopenex inhalation soln, generic levalbuterol inhalation soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - The patient has a history of failure, contraindication, or intolerance to treatment with albuterol inhalation solution	

2 . Revision History

Date	Notes

1/26/2021	Copy NY to AZ and fix guideline name for PA CHIP

Xuriden

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-64569
Guideline Name	Xuriden
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	5/1/2020

1 . Criteria

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of a hereditary orotic aciduria	

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xuriden therapy	

2 . Revision History

Date	Notes
3/31/2020	Bulk copy C&S New York SP to C&S Arizona SP for 5/1 effective

Zeposia (ozanimod)

Prior Authorization Guideline

Guideline ID	GL-129585
Guideline Name	Zeposia (ozanimod)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least TWO of the preferred alternatives * (May require PA) (Verified via pharmacy paid claims or submission of medical records)

- Interferon Beta-1B (Extavia)
- Fingolimod (Gilenya)
- Brand Copaxone 20mg
- Brand Glatopa 40mg
- Interferon Beta-1A (Refib, Avonex)

Notes	*Preferred alternatives may require PA

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting BOTH of the following*:

3.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies (document drug, date, and duration of trial):

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following** (document drug, date, and duration of trial):

- Humira (adalimumab) OR Enbrel (etanercept)
- Infliximab
- Xeljanz oral tablet (tofacitinib)

Notes	*PA may be required **Patients requesting initial authorization who were established on the rapy via the receipt of a manufacturer supplied sample at no cost in th e prescriber's office or any form of assistance from manufacturer spon sored programs shall be required to meet initial authorization criteria a s if patient were new to therapy.

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Documentation of positive clinical response to therapy **AND** **2** - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
8/15/2023	Updated criteria for UC indication

Zimhi (naloxone)

Prior Authorization Guideline

Guideline ID	GL-115900
Guideline Name	Zimhi (naloxone)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Zimhi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of failure or intolerance to preferred* naloxone products (e.g., Brand Narcan nasal spray, Kloxxado, preferred naloxone injections)	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

2 . Revision History

Date	Notes
10/24/2022	New guideline

Zokinvy

Prior Authorization Guideline

Guideline ID	GL-83975
Guideline Name	Zokinvy
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	6/1/2021

1 . Criteria

Product Name: Zokinvy	
Diagnosis	Hutchinson-Gilford Progeria Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Hutchinson-Gilford Progeria Syndrome	

Product Name: Zokinvy	
Diagnosis	Progeroid Laminopathies
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of processing deficient Progeroid Laminopathies

AND

2 - Documentation of ONE of the following:

- Heterozygous LMNA mutation with progerin-like protein accumulation
- Homozygous or compound heterozygous ZMPSTE24 mutations

Zolgensma (onasemnogene abeparvovec-xioi)

Prior Authorization Guideline

Guideline ID	GL-125352
Guideline Name	Zolgensma (onasemnogene abeparvovec-xioi)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Zolgensma	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - The mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

1.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

1.2 Compound heterozygous mutation of SMN1 gene [e.g., deletion of Survival of Motor Neuron 1 (SMN1) exon 7 (allele 1) and mutation of SMN1 (allele 2)]

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Diagnosis of diagnosis of SMA Type 0, I, or Type II spinal muscular atrophy (SMA) confirmed by a neurologist with expertise in the treatment of SMA

AND

2.1.2 Patient is less than or equal to 2 years of age

OR

2.2 BOTH of the following:

2.2.1 Diagnosis of SMA based on the results of SMA newborn screening

AND

2.2.2 Patient has 3 copies or less of Survival of Motor Neuron 2 (SMN 2)

AND

3 - Patient is NOT dependent on either of the following:

- Invasive ventilation or tracheostomy
- Use of invasive ventilation beyond use of naps and nighttime sleep

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting patient's anti-AAV9 antibody titers are less than or equal to 1:50

AND

5 - Patient is NOT to receive concomitant SMN modifying therapy (e.g., Spinraza)

AND

6 - Prescribed by a neurologist with expertise in the diagnosis of SMA

AND

7 - Patient has never received Zolgensma treatment in their lifetime

2 . Revision History

Date	Notes
5/4/2023	Updated GPI's, cleaned up criteria, removed endnotes and reference s.

Zontivity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-74804
Guideline Name	Zontivity
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2020

1 . Criteria

Product Name: Zontivity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- History of myocardial infarction (MI)
- Peripheral arterial disease (PAD)

AND

2 - Patient does not have a history of ONE of the following:

- Stroke
- Transient ischemic attack (TIA)
- Intracranial hemorrhage (ICH)

AND

3 - Patient does not have active pathological bleeding

Zortress

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110321
Guideline Name	Zortress
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Zortress	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Kidney transplant rejection prophylaxis in patients at low-moderate immunologic risk

OR

2 - Liver transplant rejection prophylaxis

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22

Zoryve (roflumilast)

Prior Authorization Guideline

Guideline ID	GL-136053
Guideline Name	Zoryve (roflumilast)
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Zoryve	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting a diagnosis of plaque psoriasis

AND

2 - Patient is 6 years of age or older

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting a minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies:

- Corticosteroids (e.g., betamethasone, clobetasol)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Zoryve	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting positive clinical response to therapy as evidenced by ONE of the following:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

2 . Revision History

Date	Notes

11/7/2023	Added age criterion due to expanded age approval.

Ztalmy (ganaxolone)

Prior Authorization Guideline

Guideline ID	GL-115901
Guideline Name	Ztalmy (ganaxolone)
Formulary	• Medicaid - Community & State Arizona SP

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Ztalmy	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

AND

2 - Patient has a mutation in the CDKL5 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Patient is experiencing motor seizures (e.g., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal, or bilateral tonic-clonic)

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to two preferred* anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine)

OR

5.2 For continuation of prior therapy

AND

6 - Prescribed by or in consultation with a neurologist

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP

Product Name: Ztalmy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by a reduction in the frequency of seizures from baseline

2 . Revision History

Date	Notes
10/24/2022	New guideline

Zyvox

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-110371
Guideline Name	Zyvox
Formulary	• Medicaid - Community & State Arizona

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Labeled Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 BOTH of the following:

1.3.1 ONE of the following diagnoses:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Skin and skin structure infections (complicated and uncomplicated)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Zyvox

OR

1.4 Invasive infection caused by or likely to be caused by vancomycin-resistant Enterococcus faecium (VRE)

Notes	*Approval Duration: For vancomycin-resistant Enterococcus faecium, authorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All other approvals will be issued for 14 days.

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Off label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR **2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **3** - The medication is being prescribed by or in consultation with an Infectious Disease specialist	
Notes	*Approval Duration: Based on provider recommended treatment durations, not to exceed 6 months.

2 . Revision History

Date	Notes
8/4/2022	C&S to match AZM as of 10.1.22