UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 2172-11 |
| Program | Prior Authorization/Medical Necessity |
| Medications | *Nucala® (mepolizumab)<br>* This program applies to the prefilled autoinjector and prefilled syringe formulations. |
| P&T Approval Date | 8/2019, 4/2020, 8/2020, 3/2021, 6/2021, 9/2021, 11/2021, 2/2022, 6/2022, 6/2023, 7/2023 |
| Effective Date | 10/1/2023;<br>Oxford only: 10/1/2023 |

**1. Background:**

Nucala (mepolizumab) is an interleukin-5 receptor antagonist indicated for add-on maintenance treatment of patients aged 6 years and older with severe asthma and with an eosinophilic phenotype, for add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP) and an inadequate response to nasal corticosteroids, the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA), and the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause[1].

Limitations of use:
Nucala is not for relief of acute bronchospasm of status asthmaticus.

**2. Coverage Criteria[a]:**

**A. Eosinophilic granulomatosis with polyangiitis (EGPA)**

1. **Initial Authorization**

a. **Nucala** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for EGPA under an active UnitedHealthcare prior authorization

**-AND-**

(b) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

i. Reduction in the frequency and/or severity of relapses
ii. Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
iii. Disease remission
iv. Reduction in severity or frequency of EGPA-related symptoms

**-AND-**

(c) Patient is not receiving Nucala in combination with **any** of the following:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(d) Prescribed by **one** of the following:

i. Pulmonologist
ii. Rheumatologist
iii. Allergist
iv. Immunologist

**-OR-**

(2) **All** of the following:

(a) Diagnosis of relapsing or refractory EGPA as defined by **all** of the following:

i. Diagnosis of EGPA

**-AND-**

ii. Past medical history or presence of asthma

**-AND-**

iii. Presence of at least **two** of the following characteristics typical of EGPA:
- Histopathological evidence of:
  - Eosiophilic vasculitis
  - Pervascular eosinophilic infiltration
  - Eosinophil-rich granulomatous inflammation
- Neuropathy, mono or poly (motor deficit or nerve conductionabnormality)
- Pulmonary infiltrates, non-fixed
- Sino-nasal abnormality
- Cardiomyopathy (established by echocardiography or MRI)
- Glomerulonephritis (hematuria, red cell casts, proteinuria)
- Alveolar hemorrhage
- Palpable purpura
- Anti-neutrophil cytoplasmic antibody (ANCA) positive

**-AND-**

iv. History of relapsing or refractory disease defined as **one** of the following:
- Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)
- Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

**-AND-**

(b) Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisone, methylprednisolone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)]

**-AND-**

(c) Patient is not receiving Nucala in combination with **any** of the following:

i. Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra(benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(d) Prescribed by **one** of the following:

i. Pulmonologist
ii. Rheumatologist
iii. Allergist
iv. Immunologist

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Nucala** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency and/or severity of relapses
(b) Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant

(c) Disease remission
(d) Reduction in severity or frequency of EGPA-related symptoms

**-AND-**

(2) Patient is not receiving Nucala in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
(d) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**Authorization will be issued for 12 months.**

**B. Severe Asthma**

1. **Initial Authorization**

a. **Nucala** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for severe asthma under an active UnitedHealthcare prior authorization

**-AND-**

(b) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

i. Reduction in the frequency of exacerbations
ii. Decreased utilization of rescue medications
iii. Increase in percent predicted FEV1 from pretreatment baseline
iv. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
v. Reduction in oral corticosteroid requirements

**-AND-**

(c) Nucala is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

**-AND-**

(d) Patient is not receiving Nucala in combination with **any** of the following:

i. Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE-therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(e) Prescribed by **one** of the following:

i. Pulmonologist
ii. Allergist
iii. Immunologist

**-OR-**

(2) **All** of the following:

(a) Diagnosis of severe asthma

**-AND-**

(b) Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following:

i. 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)
ii. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
iii. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
iv. 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])
v. Patient is currently dependent on oral corticosteroids for the treatment of asthma

**-AND-**

(c) Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level ≥ 150 cells/µL

**-AND-**

(d) Nucala will be used in combination with **one** of the following:

i. **One** maximally dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

**-OR-**

ii. Combination therapy including **both** of the following:

- **One** maximally dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

**-AND-**

- **One** additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

**-AND-**

(e) Patient is not receiving Nucala in combination with **any** of the following:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(f) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Pulmonologist

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Nucala** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency of exacerbations
(b) Decreased utilization of rescue medications
(c) Increase in percent predicted FEV1 from pretreatment baseline
(d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
(e) Reduction in oral corticosteroid requirements

**-AND-**

(2) Nucala is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

**-AND-**

(3) Patient is not receiving Nucala in combination with any of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
(d) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**Authorization will be issued for 12 months.**

**C. Hypereosinophilic Sydrome (HES)**

1. **Initial Authorization**

a. **Nucala** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for HES under an active UnitedHealthcare prior authorization

**-AND-**

(b) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

i. Reduction in frequency of HES flares
ii. Maintenance or reduction in background HES therapy requirements

**-AND-**

(c) Patient is not receiving Nucala in combination with **any** of the following:

i. Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(d) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Hematologist
iv. Cardiologist
v. Pulmonologist

**-OR-**

(2) All of the following:

(a) Diagnosis of HES ≥ 6 months ago

**-AND-**

(b) **Both** of the following:

i. There is no identifiable non-hematologic secondary cause of the patient's HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

**-AND-**

ii. HES is not FIP1L1-PDGFRα kinase-positive

**-AND-**

(c) Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting **both** of the following:

i. Baseline (pre-mepolizumab treatment) blood eosinophil level ≥1000 cells/µL within the past 4 weeks

**-AND-**

ii. Patient is currently receiving a stable dose of background HES therapy (e.g., oral corticosteroid, immunosuppressor, or cytotoxic therapy)

**-AND-**

(d) Patient is not receiving Nucala in combination with **any** of the following:

i. Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(e) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Hematologist
iv. Cardiologist
v. Pulmonologist

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Nucala** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

i. Reduction in frequency of HES flares
ii. Maintenance or reduction in background HES therapy requirements

**-AND-**

(2) Patient is not receiving Nucala in combination with **any** of the following:

i. Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**Authorization will be issued for 12 months.**

**D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

1. **Initial Authorization**

a. **Nucala** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for CRSwNP under an active UnitedHealthcare prior authorization

**-AND-**

(b) Documentation of positive clinical response to Nucala therapy

**-AND-**

(c) Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

**-AND-**

(d) Patient is **not** receiving Nucala in combination with **any** of the followng:

i. Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(e) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Otolaryngologist
iv. Pulmonologist

**-OR-**

(2) **All** of the following:

(a) Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) defined by **all** of the following:

i. **Two or more** of the following symptoms for longer than 12 weeks duration:
- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

**-AND-**

ii. **One** of the following findings using nasal endoscopy and/or sinus computed tomography (CT):
- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus
- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

**-AND-**

iii. **One** of the following:
- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

**-AND-**

iv. **One** of the following:
- Patient has required prior sinus surgery
- Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years
- Patient has been unable to obtain symptom relief after trial of **two** of the following classes of agents:
  - Nasal saline irrigations
  - Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)^
  - Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

**-AND-**

(b) Patient will receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

**-AND-**

(c) Patient is **not** receiving Nucala in combination with **any** of the following:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**-AND-**

(d) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Otolaryngologist
iv. Pulmonologist

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Nucala** will be approved based on **all** of the following criterion:

(1) Documentation of positive clinical response to Nucala therapy

**-AND-**

(2) Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

**-AND-**

(3) Patient is **not** receiving Nucala in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
(d) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
^Tried/failed alternative(s) are supported by FDA labeling.

**3. Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.
- Medical Necessity may be in place.
- The single-dose vial is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy: "Respiratory Interleukins (Cinqair®, Fasenra®, and Nucala®)".

**4. References:**

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| Program | Prior Authorization/Notification - Nucala (mepolizumab) |
|---|---|
| **Change Control** | |
| 8/2019 | New program. |
| 4/2020 | Updated program to address specific product formulations. Updated references. |
| 8/2020 | Annual review. Updated background and references. |
| 3/2021 | Updated program to add HES indication. Added limitations of use. Updated references. |
| 6/2021 | Added criteria if patient has been approved and received initial dose of Nucala directly monitored by a healthcare professional without reaction. |
| 9/2021 | Added coverage criteria for new indication, chronic rhinosinusitis with nasal polyps. Updated background and references. |
| 11/2021 | Added coverage criteria for patients established on therapy under UnitedHealthcare medical benefit. Removed prescriber requirement for reauthorization. |
| 2/2022 | Added Tezspire to list of agents not to be used in combination with Nucala for all indications. Updated coverage criteria for CRSwNP. Updated references. Added footnote to support FDA labeled first line requirements. |
| 6/2022 | Added pulmonologist to list of appropriate prescribers in section for patients established on therapy with Nucala for CRSwNP. |
| 6/2023 | Annual review. Updated examples of standard therapy for EGPA and added examples of oral corticosteroids within Asthma criteria. Updated background and references. |
| 7/2023 | Updated EGPA standard therapy examples. Updated coverage criteria for severe asthma to align with GINA & ERS/ATS guidelines. Added/updated examples of ICS-containing maintenance medications, removed requirement that peripheral blood eosinophil level must be within 6 weeks, and removed bypass of eosinophilic phenotype requirement for patients currently dependent on maintenance therapy with oral corticosteroids. Updated references. |