



**UnitedHealthcare Individual & Family ACA Marketplace Plans  
Clinical Pharmacy Program Guidelines for Overactive Bladder Agents**

Program	Step Therapy
Medication	Darifenacin (generic Enablex), Solifenacin (generic Vesicare), Tolterodine (generic Detrol)
Issue Date	9/2020
Pharmacy and Therapeutics Approval Date	11/2022
Effective Date	2/2023

**1. Background:**

Darifenacin, Solifenacin, and Tolterodine are indicated for the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge-related urinary incontinence.

Oxybutynin is indicated for the treatment of OAB with symptoms of urinary frequency, urinary urgency, or urinary incontinence due to involuntary detrusor muscle contractions (includes neurogenic bladder), and for the relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria).

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try oxybutynin (generic Ditropan) prior to receiving coverage for darifenacin, solifenacin, or tolterodine.

**2. Coverage Criteria<sup>a</sup>:**

<p><b>A. Darifenacin, Solifenacin, or Tolterodine</b> will be approved based on the following criteria:</p> <ol style="list-style-type: none"><li>History of failure, contraindication, or intolerance to oxybutynin (generic Ditropan) or oxybutynin ER (generic Ditropan XL).</li></ol> <p align="center"><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> 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.</p>
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**3. Additional Clinical Rules:**

- 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 limits may be in place.

#### 4. References:

1. Detrol [package insert]. New York, NY: Pfizer Inc., September 2021.
2. Ditropan XL [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021.
3. Darifenacin [package insert]. Florham Park, NJ. Xiromed, LLC. April 2021.
4. Oxybutynin chloride syrup [package insert]. Philadelphia, PA: Lannett Company, Inc., February 2020.
5. Oxybutynin chloride tablet [package insert]. Princeton, NJ: Eywa Pharma Inc., July 2019.
6. Vesicare [package insert]. Northbrook, IL: Astellas Pharma UC, Inc., June 2020.

Program	Step Therapy - Overactive Bladder Agents
<b>Change Control</b>	
Date	Change
6/2009	Criteria taken from previously approved AmeriChoice policy. Policy reformatted. Vesicare added to policy.
12/2010	Annual review, no changes
12/2011	Annual review, updated references
12/2012	Updated preferred drug list. Removed Vesicare and Enablex as preferred and added Detrol and Sanctura as preferred. Updated references
11/2016	Annual review, updated policy template and references. Add standard authorization duration of 12 months.
4/2017	Updated background. Removed step therapy on oxybutynin extended-release. Updated preferred/non-preferred product list. Added non-preferred criteria.
8/2017	Moved automated step therapy criteria to the background. Updated the non-preferred product language.
9/2018	Annual review, updated background and references.
12/2019	Annual review, updated background and references. Minor updates made to criteria with no change to clinical intent.
10/2020	Revised C&S PA policy to Step Therapy policy, revised background, referenced only formulary generic oxybutynin as an alternative, and added references as appropriate.
11/2020	Updated ST Descriptions and alternatives to align build file and set up for UHC Value & Balance Exchange for 1/2021 implementation.
9/2021	Review for 2022 implementation, removed markets in scope and detailed definition of step therapy from the background.
11/2022	Annual review, updated references.

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