UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Overactive Bladder Agents

Program	Step Therapy
Medication	Preferred: oxybutynin syrup, oxybutynin tablet, oxybutynin extended-release tablet, Oxytrol for Women (oxybutynin OTC) patch Preferred with Step Therapy: tolterodine tablet, trospium tablet Non-Preferred: Oxytrol (oxybutynin Rx) patch, Detrol LA (tolterodine) extended-release capsule, flavoxate tablet, trospium extended-release capsule, Enablex (darifenacin) extended-release tablet, Toviaz (fesoterodine) extended-release tablet, Vesicare (solifenacin) tablet , Myrbetriq (mirabegron) extended-release tablet, Gelnique (oxybutynin) topical gel, Ditropan XL (oxybutynin) extended-release tablet, Detrol (tolterodine) tablet
Markets in Scope	Hawaii, Colorado, California, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	3/2021

1. Background:

Trospium and tolterodine are indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and frequency.

Oxybutynin is indicated 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).

2. Coverage Criteria:

A. Preferred Product Requests

1. Tolterodine IR or trospium will be approved when **one** of the following circumstances is met:

    a. The patient has a history of failure, contraindication or intolerance to treatment with oxybutynin

    -OR-

    b. The patient is greater than or equal to 65 years of age.

    Authorization will be issued for 12 months.

B. Non-Preferred Requests

One of the following:

1. Oxytrol (oxybutynin Rx) patch, Detrol LA (tolterodine) extended-release capsule, trospium extended-release capsule, Enablex (darifenacin) extended-release tablet, Toviaz (fesoterodine) extended-release tablet, Vesicare (solifenacin) tablet , Myrbetriq (mirabegron) extended-release tablet, Gelnique (oxybutynin) topical gel, Ditropan XL (oxybutynin) extended-release tablet, or Detrol (tolterodine) tablet will be approved based on the following:

    a. The patient has a history of failure, contraindication, or intolerance to a trial of at least three preferred products, one of which MUST be oxybutynin extended release tablet

    -OR-

2. Flavoxate will be approved based on the following

    a. The patient has a history of failure, contraindication, or intolerance to a trial of at least three preferred products

Authorization will be issued for 12 months.

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] NY, NY: Pfizer Inc., October 2016.
2. Detrol LA [package insert] NY, NY: Pfizer Inc., July 2018.
3. Ditropan XL [package insert] Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2018.
4. Enablex [package insert] Irvine, CA: Allergan; September 2016.
5. Flavoxate hydrochloride tablet [package insert] Laurelton, NY: Epic Pharma, LLC; May 2018.
6. Gelnique [package insert] Irvine, CA: Allergan; March 2019.
7. Myrbetriq [package insert] Northbrook, IL: Astellas Pharma UC, Inc.; April 2018.
8. Oxybutynin chloride syrup [package insert] Philadelphia, PA: Lannett Company, Inc.; February 2020.
9. Oxybutynin chloride tablet [package insert] Princeton, NJ: Eywa Pharma Inc.; May 2019.
10. Oxytrol [package insert] Irvine, CA: Allergan; September 2017.
11. Toviaz [package insert] NY, NY: Pfizer Inc.; November 2017.
12. Trospium extended release capsule [package insert] Parsippany, NJ. Actavis Pharma, Inc.; August 2014.
13. Trospium chloride tablet [package insert] Weston, FL: Apotex Corp.; Aug 2019.
14. Vesicare [package insert] Northbrook, IL: Astellas Pharma UC, Inc.; May 2020.

Program	Overactive Bladder Agents –Prior Authorization
Change Control	
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.
12/2020	Annual review, updated references.