

Clinical Pharmacy Program Guidelines for Overactive Bladder Agents

Program	Step Therapy
Medication	<p>Preferred: Oxybutynin syrup, oxybutynin tablet, oxybutynin extended-release tablet, Oxytrol for Women (OTC) patch</p> <p>Preferred with Step Therapy: Tolterodine tablet, trospium tablet</p> <p>Non-Preferred: Oxytrol (Rx) patch, tolterodine extended-release capsule, flavoxate, trospium extended-release capsule, darifenacin extended-release tablet, Toviaz, Vesicare, Myrbetriq, Gelnique</p>
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	8/2017
Effective Date	10/2017

1. Background:

Trospium is indicated for the treatment of overactive bladder (OAB) with symptoms of urgency, frequency, and urge urinary incontinence.

Tolterodine is indicated for the treatment of 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).

Automated Step Therapy Criteria

A claim for tolterodine IR or trospium will process at the point of sale if the patient’s drug fill history shows a 30 day trial of oxybutynin

2. Coverage Criteria:

A. Preferred Product Requests

1. Tolterodine IR or tropsium will be approved for patients who have not met the automated step criteria when **one** of the following circumstances is met:

- a. The patient did not exhibit an adequate response to treatment with oxybutynin

-OR-

- b. The patient experienced an intolerance/adverse reaction to previous therapy with oxybutynin

-OR-

- c. The patient has a documented contraindication to treatment with oxybutynin

-OR-

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

B. Non-Preferred Requests

One of the following:

1. Oxytrol (Rx) patch, tolterodine extended-release capsule, tropsium extended-release capsule, darifenacin extended-release tablet, Toviaz, Vesicare, Myrbetriq, or Gelnique 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. References:

1. Ditropan XL Prescribing Information. Ortho-McNeil, June 2011.
2. Detrol Prescribing Information. Pfizer, August 2012.
3. Sanctura Prescribing Information. Allergan, July 2012.
4. Appell RA. Pharmacotherapy for overactive bladder: an evidence-based approach to selecting an antimuscarinics agent. *Drugs* 2006; 66(10):1361-70.
5. Erdem N, Chu F. Management of overactive bladder disease and urge urinary incontinence in the elderly patient. *Amer J of Med* 2006; 119:29-36.
6. Hesch K. Agents for the treatment of overactive bladder: a therapeutic class review. *Baylor University Medical Center* 2007; 20(3):307-14.
7. Yoshimura N, Chancellor MB. Current and future pharmacological treatment for overactive bladder. *J of Urology* 2002; 168:1897-1913.
8. Chu FM, Dmochowski RR, Lama DJ, et al. Extended-release formulations of oxybutynin and tolterodine exhibit similar central nervous system tolerability profiles: A sub-analysis of data from the OPERA trial. *Amer J of Ob and Gyn* 2005; 192(6):1849-55.
9. Facts and Comparisons 4.0 2012.

Program	Overactive Bladder Agents –Prior Authorization
Change Control	
Date	Change
June 2009	Criteria taken from previously approved AmeriChoice policy. Policy reformatted. Vesicare added to policy.
Dec 2010	Annual review, no changes
Dec 2011	Annual review, updated references
Dec 2012	Updated preferred drug list. Removed Vesicare and Enablex as preferred and added Detrol and Sanctura as preferred. Updated references
Nov 2016	Annual review, updated policy template and references. Add standard authorization duration of 12 months.
April 2017	Updated background. Removed step therapy on oxybutynin extended-release. Updated preferred/non-preferred product list. Added non-preferred criteria.
Aug 2017	Moved automated step therapy criteria to the background. Updated the non-preferred product language.