MEDICAL MUTUAL®

# Drug Policy

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| **Policy:**<br><br>**Impacted Drugs:** | **Overactive Bladder Medications**<br>**Preferred Step Therapy Policy**<br><br>• Darifenacin extended-release tablets<br>• Oxytrol (prescription)<br>• Oxytrol for Women (over-the-counter)<br>• Toviaz<br>• Trospium chloride extended-release capsules<br>• Vesicare<br>• Vesicare LS | **Annual Review Date:**<br>**11/21/2023**<br><br>**Last Revised Date:**<br>**11/21/2023** |

## OVERVIEW

These products, except oxybutynin tablets and syrup and Vesicare LS, are indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. Gemtesa and Myrbetriq are beta3-adrenergic agonists; the other products are antimuscarinics. Myrbetriq is indicated for use as monotherapy or in combination with solifenacin.

The Oxytrol transdermal patch is available as a prescription and an over-the-counter (OTC) product. Prescription Oxytrol is indicated for the treatment of OAB in men with symptoms of urge urinary incontinence, urgency, and frequency. The OTC formulation is marketed as Oxytrol for Women and is indicated for use in women ≥ 18 years of age. The prescription and OTC Oxytrol contain the same dose of oxybutynin (3.9 mg/day).

## POLICY STATEMENT

A step therapy program has been developed to encourage use of one preferred product prior to the use of a non-preferred product. If the step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

**Automation:** Patients with a history of one preferred drug within the 130-day look-back period are excluded from step therapy.

**Preferred Agents:**

- Fesoterodine extended-release tablets
- Myrbetriq (tablets, granules)
- oxybutynin immediate-release tablets
- oxybutynin immediate-release syrup
- oxybutynin extended-release tablets
- trospium chloride tablets

**Non-Preferred Agents:**

- darifenacin extended-release tablets
- Oxytrol (prescription)
- Oxytrol for Women (over-the-counter)
- solifenacin succinate tablets
- tolterodine tartrate tablets
- tolterodine tartrate extended-release capsules
- Toviaz
- trospium chloride extended-release capsules
- Vesicare
- Vesicare LS

**CRITERIA**

1. If the patient has tried a preferred agent, then authorization for a non-preferred agent may be given.

2. If the patient is < 3 years of age, approve Vesicare LS.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 365 days
**B)** *Extended Approval:* 365 days

**Step Therapy Exception Criteria**
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the

requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

**Documentation Required:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

**Approval Duration:** All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

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**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

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10. Enablex extended-release tablets [prescribing information]. Rockaway NJ: Warner Chilcott; October 2013.
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12. Gelnique 10% gel [prescribing information]. Parsippany, NJ: Actavis Pharma; July 2015.
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17. Ouslander JG. Management of overactive bladder. *N Engl J Med*. 2004;350(8):786-799.
18. Product Information: VESICARE LS(TM) oral suspension, solifenacin succinate oral suspension. Astellas Pharma US Inc (per FDA), Northbrook, IL, 2020.

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