# Pharmacy Medical Necessity Guidelines: Overactive Bladder Medications

*Effective: April 1, 2020*

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| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review | RXUM |

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

Overactive bladder (OAB) is a form of urinary incontinence affecting both male and female patients of all ages. Signs and symptoms of OAB include urgency (defined as a sudden need to urinate), frequency (defined as emptying the bladder more than eight times per day), and nocturia with or without incontinence. The International Continence Society defines OAB as urgency, with or without urge incontinence, usually with frequency and nocturia. The prevalence of OAB increases with age and patients with a history of pelvic surgery, dementia, or diabetes may be at an increased risk of developing this condition.

Bladder contraction is primarily under control of the parasympathetic nervous system and anticholinergics are considered to be the pharmacologic treatment of choice for OAB. These agents work through the non-selective inhibition of acetylcholine on muscarinic receptors in smooth muscle throughout the body. Research suggests that the muscarinic$_3$ ($M_3$) receptor, located on bladder smooth muscle, is the predominate factor responsible for bladder contraction (i.e., these anticholinergics prevent unintentional bladder contraction). In addition, the $M_3$ receptor mediates saliva production, gastrointestinal smooth muscle, and iris sphincter function; therefore, expected side effects of anticholinergics include dry mouth, constipation, and miosis. Some newer agents for OAB have a stronger affinity for the $M_3$ receptor compared to other anticholinergic agents and therefore have comparable efficacy but a proposed lower side effect profile. The beta-3 adrenergic agonists have a novel mechanism of action and work by relaxing the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of the beta-3 adrenergic receptor, which increases bladder capacity. The beta-3 adrenergic agonists offer an alternative treatment option for patients who cannot tolerate the adverse events from the anticholinergic agents. Myrbetriq (mirabegron) is the only beta-3 adrenergic agonists available. All other available overactive bladder medications are anticholinergics.

## FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Darifenacin, Gelnique (oxybutynin), Myrbetriq (mirabegron), Oxytrol (oxybutynin), and Toviaz (fesoterodine) are all indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and frequency.

## COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred overactive bladder medication for Members when **all** the following criteria are met:

1. Documentation the Member has had an insufficient response or intolerable adverse effect to therapy with at least two alternative medications* for overactive bladder, including at least one long-acting formulation

***Preferred alternative medications include: flavoxate, oxybutynin immediate-release and extended-release tablets, oxybutynin transdermal (Oxytrol OTC), solifenacin, tolterodine immediate-release tablets and extended-release capsules, and trospium immediate-release tablets and extended-release capsules.**

## LIMITATIONS

None

## CODES

None

## REFERENCES


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## APPROVAL HISTORY

April 14, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. January 1, 2016: Administrative change to rebranded template.
2. March 8, 2016: Added flavoxate to the list of preferred alternative medications. Removed Limitation #1 "Approval length will be for life of plan."
3. March 14, 2017: No changes.
4. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
5. December 11, 2018: Administrative changes made to template.
6. November 12, 2019: Updated MNG to indicate that solifenacin is a preferred product. Effective 4/1/2020, updated MNG to indicate that Toviaz requires prior authorization.
7. January 14, 2020: Effective 1/20/20, removed trial and failure with Oxytrol for Women for approval female members requesting Gelnique or Oxytrol patch.

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services