Pharmacy Medical Necessity Guidelines:
Overactive Bladder Medications

Effective: September 9, 2025

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

Myrbetriq, Toviaz, and Vesicare LS are indicated for the treatment of neurogenic detrusor overactivity (NDO). Vesicare LS is approved for this indication in pediatric patients 2 years and older. Myrbetriq granules are approved for NDO in pediatric patients 3 years of age and older, while Myrbetriq tablet is approved for the treatment of NDO in patients who are at least 3 years of age and weigh at least 35 kilograms. Toviaz is approved for the treatment of NDO in patients 6 years of age and older who weigh at least 25 kilograms. Oxybutynin extended-release (Ditropan XL) is approved for patients 6 years of age and older with symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida). Oxybutynin tablet and syrup are indicated for the relief of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder; both have been studied in patients 5 years of age and older. Oxybutynin immediate-release and extended-release tablets as well as oxybutynin syrup are covered without Prior Authorization for Tufts Health RITogether.

COVERAGE GUIDELINES

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

Darifenacin, Gelnique, Gemtesa, and Oxytrol

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

Vesicare LS

1. Member is 2 years of age or older

AND

2. Member has a diagnosis of neurogenic detrusor overactivity

AND

3. **Members 6 years of age and older:** Member has had an inadequate response, intolerance, or contraindication to oxybutynin

Myrbetriq tablet, granules

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

OR

2. The Member meets all of the following:
    a. The Member is 3 years of age or older

    AND

    b. The Member has a diagnosis of neurogenic detrusor overactivity

    AND

    c. **Members 6 years of age and older:** Member has had an inadequate response, intolerance, or contraindication to oxybutynin

Toviaz

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

OR

2. The Member meets all of the following:
    a. The Member is 6 years of age or older

    AND

    b. The Member has a diagnosis of neurogenic detrusor overactivity

    AND

    c. Member has had an inadequate response, intolerance, or contraindication to oxybutynin

***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

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: No changes.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes

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