Pharmacy Medical Necessity Guidelines: Overactive Bladder Medications Step Therapy

Effective: January 1, 2021

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
MM: 888.415.9055
PRECERT: 617.972.9409

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

OVERVIEW

Overactive bladder (OAB) is a form of urinary incontinence affecting patients of all ages.

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Flavoxate is indicated for symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, and urethrocystitis/urethrotrigonitis.

Detrol (tolterodine), Detrol LA (tolterodine), Ditropan XL (oxybutynin), Enablex (darifenacin), Gelnique (oxybutynin), Myrbetriq (mirabegron), oxybutynin extended- and immediate-release, trospium extended- and immediate-release, tolterodine extended- and immediate-release, and Vesicare (solifenacin) are all indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and frequency.

Ditropan XL (oxybutynin) is also indicated for the treatment of pediatric patients aged six years and older with symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida).

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
darifenacin	Covered	Covered
flavoxate		
oxybutynin		
oxybutynin ER		
tolterodine		
tolterodine ER		
trospium		
trospium ER		

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
solifenacin		
Step-2		
Vesicare®	Requires prior use of a drug on Step-1 or Step-2	Not covered
Ditropan® XL		
Detrol®		
Detrol LA®		
Enablex®		
Gelnique		Requires prior use of a drug on Step-1 or Step-2
Myrbetriq™		

Automated Step Therapy Coverage Criteria
The following stepped approach applies to coverage of the Step-2 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization.
Step 2: The plan may cover medications on Step-2 if the following criteria are met:
- The Member has had a trial of one (1) Step-1 or Step-2 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale
The following stepped approach applies to overactive bladder medications covered by the plan:

Step 2: The plan may cover Step-2 medications if the following criteria are met:
- The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples

OR

- Requesting physician has documented that the member has a contraindication to or is unable to tolerate medications on Step-1

Note: The plan may cover medications on Step-2 if a Member has received one of the **non-covered** medications, listed below under the limitations section, as evidenced by physician documented use, excluding the use of samples.

LIMITATIONS

- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- The plan does not cover the following medications on all Commercial formularies: Toviaz® (fesoteridine) and Oxytrol®. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.
- The plan does not cover the following brand name medications on the MA/RI/Freedom Exchange formularies: Ditropan XL, Detrol, Detrol LA, Enablex, Vesicare. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.

CODES

None

REFERENCES

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APPROVAL HISTORY

November 11, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
2. January 12, 2010: Added Ditropan, Ditropan XL, Gelnique, Oxytrol, Sanctura and Sanctura XR to Step-1 of automated step therapy coverage guidelines. Added Detrol (tolterodine) to title of Medical Necessity Guidelines.
3. January 11, 2011: Added trospium to Step-1 of the automated step therapy coverage guidelines. Moved Sanctura to not covered for the Generic Focused Formulary (GFF).
4. September 13, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs
5. January 10, 2012: No changes
6. June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
7. August 14, 2012: Added generic tolterodine tablets to Step-1 of step therapy program. Added non-covered Toviaz (fesoterodine) as a prerequisite drug. Added use of samples or vouchers/coupons for brand name medications limitation.
8. January 15, 2013: Added generic trospium extended release tablets to Step-1 of step therapy program. Added Sanctura XR to not covered for the Generic Focused Formulary. Removed brand name Ditropan from Medical Necessity Guidelines, product discontinued.
9. February 12, 2013: Changed the title of the Medical Necessity Guideline from Detrol (tolterodine) and Detrol LA (tolterodine tartrate ext-rel) to Overactive Bladder Medications Step Therapy. Added Myrbetriq (mirabegron) to Step-2 of the Medical Necessity Guidelines and updated the FDA-Approved indications to include information on Myrbetriq (mirabegron).
10. October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
11. February 11, 2014: Added tolterodine ext-rel to Step-1 and moved Detrol and Detrol LA to Not Covered for the GFF.
12. April 1, 2014: Administrative Update: Removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI Formulary.
13. January 13, 2015: Removed Oxytrol from the medical necessity guidelines as it has been moved to Non-covered effective 1/1/15.
14. March 10, 2015: For effective date April 1, 2015: Moved Ditropan XL, Detrol, Detrol LA, Sanctura, and Sanctura XR to not covered for the MA/RI EHB formularies.
15. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
16. March 8, 2016: No changes
17. April 12, 2016: Added generic darifenacin to Step-1. Moved Enablex to Step-2 to for Large group formularies and to not covered for the MA/RI EHB formularies.
18. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
19. May 8, 2018: Updated the coverage criteria to clarify that request for Step-2 medications may be approved if the requesting physician has documented that the member has a contraindication to or is unable to tolerate medications on Step-1.
20. June 11, 2019: Administrative update to the template. Removed Sanctura and Sanctura XR from the MNG as these products are discontinued. Moved Vesicare brand to not covered for the MA/RI EHB formularies. Added generic solifenacin to step 1 drugs.
21. September 15, 2020: Effective 1/1/2021, moved Vesicare and Ditropan XL to the Step 2 of the STPA program.

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.