TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Benign Prostatic Hyperplasia 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

FDA-APPROVED INDICATIONS

Dutasteride (Avodart) is a 5 alpha-reductase inhibitor indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery. When used in combination with tamsulosin, dutasteride is indicated for the treatment of symptomatic BPH in men with an enlarged prostate.

Tadalafil (Cialis) 5 mg, a phosphodiesterase 5 (PDE5) inhibitor, is indicated for the treatment of erectile dysfunction, the signs and symptoms of benign prostatic hyperplasia (BPH), and ED and the signs and symptoms of BPH.

Jalyn, a combination of dutasteride, a 5 alpha-reductase inhibitor, and tamsulosin, an alpha adrenergic antagonist, is indicated for the treatment of symptomatic (BPH) in men with an enlarged prostate.

Silodosin (Rapaflo), a selective alpha-1 adrenoreceptor antagonist, is indicated for treatment of the signs and symptoms of benign prostatic hyperplasia.

COVERAGE GUIDELINES

The plan may authorize coverage of the following products indicated for benign prostatic hyperplasia (BPH) for Members when **ALL** the following criteria for a particular regimen are met and limitations do not apply:

Dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn)

1. The Member has the diagnosis of benign prostatic hypertrophy (BPH) or signs and symptoms of BPH

AND

2. The Member has tried and failed therapy with finasteride, or the provider indicates clinical inappropriateness of therapy with finasteride

AND

3. **Dutasteride/tamsulosin only:** Clinical rationale why the member cannot take dutasteride and tamsulosin separately

Silodosin (Rapaflo)

1. The Member has the diagnosis of benign prostatic hyperplasia (BPH) or signs and symptoms of BPH

AND

2. The Member has tried and failed therapy with both tamsulosin and alfuzosin, or the provider indicates clinical inappropriateness of treatment with both tamsulosin and alfuzosin

Tadalafil (Cialis) (for daily use)

1. The Member has a diagnosis of benign prostatic hyperplasia (BPH)

AND

2. The request is for tadalafil 5 mg once daily

AND

3. The Member has tried and failed therapy with, or has a contraindication to tamsulosin and alfuzosin

AND

4. The Member has tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with one of the 5 alpha-reductase inhibitors (e.g. finasteride or dutasteride)

LIMITATIONS

1. The coverage of dutasteride/tamsulosin and silodosin is limited to one capsule per day.
2. The coverage of tadalafil for BPH will be limited to one tablet per day.
3. Members should not concurrently administer an alpha-blocker (e.g., doxazosin, tamsulosin, alfuzosin, silodosin, or terazosin) or antihypertensives when tadalafil is taken as a once-daily maintenance regimen.
4. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria.
5. Tadalafil will not be approved for the treatment of sexual dysfunction, as this indication is excluded for RITogether.

CODES

None

REFERENCES

1. Avodart (dutasteride) [package insert]. Wixom, MI: Woodward Pharma Services LLC; August 2023 .
2. Cialis (tadalafil) [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2023.
3. Jalyn (dutasteride/tamsulosin) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; June 2024 .
4. McVary KT, Roehrborn CG, Avins AL, et al. Update on AUA guideline on the management of benign prostatic hyperplasia. J Urol. 2011;185(5):1793-1803.
5. Rapaflo (silodosin) [package insert]. Madison, NJ: Allergan USA, Inc; December 2020.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective October 1, 2023, administrative update: updated limitations section of the MNG to indicate that tadalafil will not be approved for the treatment of sexual dysfunction as this indication is excluded for RITogether.
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.