Pharmacy Medical Necessity Guidelines:
Benign Prostatic Hyperplasia Medications

Effective: October 1, 2020

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

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.

Tadalafil (Cialis), 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 hypertrophy (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 two selective alpha-blockers (e.g., tamsulosin, alfuzosin, or silodosin)

AND

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

LIMITATIONS

1. The coverage of dutasteride, 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 be using an alpha-blocker (e.g., doxazosin, tamsulosin, alfuzosin, silodosin, or terazosin) 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.

CODES

None

REFERENCES

1. Avodart (dutasteride) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; January 2020.
2. Jalyn (dutasteride/tamsulosin) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; November 2017.
3. 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.
4. Rapaflo (silodosin) [package insert]. Parsippany, NJ: Watson Pharma Inc; October 2014.
5. Cialis (tadalafil) [package insert]. Indianapolis, IN: Lilly USA, LLC; February 2018.

APPROVAL HISTORY

January 19, 2012: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 8, 2014: Phosphodiesterase-5 Inhibitors reviewed by the Pharmacy and Therapeutics Committee
2. August 12, 2014: No changes
3. August 11, 2015: Modified criteria for tadalafil, removing statement that an alpha-reductase may not be indicated if there is no prostate enlargement and added language if provider indicates clinical inappropriateness of therapy with an alpha-reductase inhibitor.
4. January 1, 2016: Administrative change to rebranded template.
5. August 9, 2016: Updated policy to reflect generic availability of Avodart and Jalyn. Added limitation "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria". Reflected the generic availability of Avodart and Jalyn.
6. April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
7. August 8, 2017: No changes.
8. August 7, 2018: No changes.
9. June 11, 2019: Administrative changes made to template.
10. May 12, 2020: Effective 10/1/2020, updated the criteria for dutasteride/tamsulosin combination product to require clinical rationale why the member cannot take dutasteride and tamsulosin separately.

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.