MEDICAL MUTUAL®

Drug Policy

Policy:	**Benign Prostatic Hyperplasia – 5-Alpha-Reductase Inhibitors Step Therapy Policy**	**Annual Review Date:** **10/17/2024**
Impacted Drugs:	dutasteride dutasteride/tamsulosin	**Last Revised Date:** **10/17/2024**

OVERVIEW

The 5-alpha-reductase inhibitors and alpha1-blockers are therapies in the treatment of symptomatic benign prostatic hyperplasia (BPH).[1] Finasteride and dutasteride are both 5-alpha reductase inhibitors indicated to improve symptoms, reduce the risk of acute urinary retention, and to reduce the need for BPH-related surgery in men with enlarged prostates.[2-4] Finasteride is also indicated to decrease the risk of symptomatic progression of BPH in combination with the alpha1-blocker doxazosin.[2] Dutasteride is also indicated for the treatment of symptomatic BPH in men with an enlarged prostate in combination with the alpha1-blocker, tamsulosin.[3,5]

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation:

A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic finasteride 5 mg, generic dutasteride

Step 2: generic dutasteride/tamsulosin

PREFERRED STEP THERAPY CRITERIA

1. If dutasteride/tamsulosin is being requested, approve if the patient has tried generic finasteride or generic dutasteride.

2. A Step 2 Product is not covered when being used for the treatment of male pattern hair loss (MPHL). MPHL is considered a cosmetic use.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years
B) *Extended Approval:* 2 years

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Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all Step 1 agents. If so, please list diagnosis and/or patient characteristics*; **OR**
B. The patient has a contraindication to all Step 1 agents. If so, please list the contraindications to each preferred agent*; **OR**
C. The patient is continuing therapy with the requested Step 2 agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested Step 2 agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested Step 2 product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested Step 2 agent for 90 days AND that the patient has been receiving the requested Step 2 agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested Step 2 agent) AND there is no generic equivalent available for the requested Step 2 product (i.e. AA-rated or AB-rated to the requested Step 2 product).

***Documentation Required:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as *. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;211:1-8.
2. Proscar® tablets [prescribing information]. Jersey City, NJ: Organon; June 2021.
3. Avodart® capsules [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2022.
4. Dutasteride capsules [prescribing information]. Bridgewater, NJ: Amneal; February 2022.
5. Jalyn® [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.