

## STEP THERAPY POLICY

- POLICY:** Benign Prostatic Hyperplasia – 5-Alpha-Reductase Inhibitors Step Therapy Policy
- Avodart® (dutasteride capsules – GlaxoSmithKline, generic)
  - Jalyn® (dutasteride/tamsulosin – GlaxoSmithKline, generic)
  - Proscar® (finasteride tablets - Organon, generic)

**REVIEW DATE:** 11/29/2023

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### OVERVIEW

The 5-alpha-reductase inhibitors and alpha<sub>1</sub>-blockers are therapies in the treatment of symptomatic benign prostatic hyperplasia (BPH).<sup>1</sup> 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.**<sup>2-4</sup> Finasteride is also indicated to **decrease the risk of symptomatic progression of BPH in combination with the alpha<sub>1</sub>-blocker doxazosin.**<sup>2</sup> Dutasteride is also indicated for the treatment of **symptomatic BPH in men with an enlarged prostate in combination with the alpha<sub>1</sub>-blocker, tamsulosin.**<sup>3,5</sup> Jalyn is the commercially available product which combines dutasteride and tamsulosin in one capsule for patients who require dual therapy.<sup>5</sup> The same dosage of dutasteride and tamsulosin can be obtained by taking the respective products individually.

### Guidelines

The American Urological Association (AUA) guidelines on the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (2023) recommends that 5-alpha-reductase inhibitors can be used by men with demonstrable prostatic enlargement.<sup>1</sup> This class of medication does have a low onset of action and alpha-blocker would provide more immediate relief for men with voiding symptoms. The 5-alpha-reductase inhibitors can be used with alpha-blocker therapy. AUA does not recommend one 5-alpha-reductase inhibitor over another.

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

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

**Step 1:** generic finasteride 5 mg

**Step 2:** Avodart, dutasteride, Jalyn, dutasteride/tamsulosin, Proscar

## CRITERIA

1. If the patient has tried the Step 1 Product, approve a Step 2 Product.
2. If the patient has tried generic finasteride or brand Proscar, approve Avodart, dutasteride, Jalyn, or dutasteride/tamsulosin.
3. A Step 2 Product is not covered when it is being used for the treatment of hair loss. Hair loss is considered a cosmetic use.
4. No other exceptions are recommended.

## 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]. Wixom, MI: Woodward; August 2022.
4. Dutasteride capsules [prescribing information]. Bridgewater, NJ: Amneal; February 2022.
5. Jalyn® [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.