

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: 11/16/2022

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} Jalyn is the commercially available product which combines dutasteride and tamsulosin in one capsule for patients who require dual therapy.⁵ 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 (2021) recommends that 5-alpha-reductase inhibitors can be used by men with demonstrable prostatic enlargement.¹ 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. Management of benign prostatic hyperplasia/lower urinary tract symptoms: American Urological Association guideline 2021. Available at: [Benign Prostatic Hyperplasia \(BPH\) Guideline - American Urological Association \(auanet.org\)](https://www.auanet.org/guidelines/management-of-benign-prostatic-hyperplasia). Accessed on November 9, 2022.
2. Proscar® tablets [prescribing information]. Jersey City, NJ: Organon; June 2021.
3. Avodart® capsules [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2020.
4. Dutasteride capsules [prescribing information]. Bridgewater, NJ: Amneal; February 2020.
5. Jalyn® [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.