

STEP THERAPY POLICY

- POLICY:** Avodart Step Therapy Program
- Avodart™ (dutasteride capsules – GlaxoSmithKline; generics)
 - Jalyn™ (dutasteride/tamsulosin – GlaxoSmithKline; generics)
 - Proscar® (finasteride tablets - Merck, generics)

REVIEW DATE: 12/09/2020

OVERVIEW

The 5 alpha-reductase inhibitors and alpha₁-blockers are commonly used 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.

The Enlarged Prostate International Comparator Study (EPICS) was a randomized, double-blind, multicenter, parallel-group trial that compared the efficacy of finasteride (5 mg/day) and dutasteride (0.5 mg/day) over 12 months in 1,630 patients with BPH.⁶ There were no statistically significant differences between the treatment groups in the change in prostate volume, symptom improvement, or urinary flow rate.

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 history 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 Avodart, dutasteride, Jalyn, or dutasteride/tamsulosin is being requested, approve if the patient has tried generic finasteride or brand Proscar.
3. 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.
4. No other exceptions are recommended.

REFERENCES

1. Chapple CR. Pharmacological therapy of benign prostatic hyperplasia/lower urinary tract symptoms: an overview for the practicing clinician. *BJU Int.* 2004;94(5):738-744.
2. Proscar[®] tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc; September 2013.
3. Avodart[™] capsules [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2020.
4. Dutasteride capsules [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals; February 2020.
5. Jalyn [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; November 2017.
6. Nickel JC, Gilling P, Tammela TL, et al. Comparison of dutasteride and finasteride for treating benign prostatic hyperplasia: the Enlarged Prostate International Comparator Study (EPICS). *BJU Int.* 2011;108:388-394.