



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: 12/11/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 (2023) recommends that 5-alpha-reductase inhibitors can be used by men with

demonstrable prostatic enlargement.¹ This class of medication does have a slow 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.

Step 1: generic finasteride 5 mg

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

Benign Prostatic Hyperplasia – 5-Alpha-Reductase Inhibitors Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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.

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; November 2023.
3. Avodart® capsules [prescribing information]. Wixom, MI: Woodward; October 2023.
4. Dutasteride capsules [prescribing information]. Bridgewater, NJ: Amneal; August 2023.
5. Jalyn® [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; April 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/29/2023

Annual Revision	No criteria changes.	12/11/2024
-----------------	----------------------	------------

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.