# Clinical Policy: Dutasteride (Avodart), Dutasteride/Tamsulosin (Jalyn)

Reference Number: CP.PMN.128
Effective Date: 05.01.16
Last Review Date: 05.22
Line of Business: Commercial, HIM, Medicaid Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
The following are benign prostatic hyperplasia (BPH) agents requiring prior authorization: dutasteride (Avodart®) and dutasteride/tamsulosin (Jalyn®).

**FDA Approved Indication(s)**
Avodart is indicated:

- For the treatment of symptomatic BPH in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery
- In combination with the alpha-adrenergic antagonist, tamsulosin, for the treatment of symptomatic BPH in men with an enlarged prostate.

Jalyn is indicated:

- For the treatment of symptomatic BPH in men with an enlarged prostate.

Limitation(s) of use: Dutasteride-containing products, including Avodart and Jalyn, are not approved for the prevention of prostate cancer.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Avodart and Jalyn are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Benign Prostatic Hyperplasia** (must meet all)**:**

1. Diagnosis of BPH;
2. Age ≥ 18 years;
3. Failure of 2 formulary agents indicated for BPH (e.g., doxazosin, finasteride, prazosin, tamsulosin, terazosin) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. If request is for brand Avodart or Jalyn, member must use the corresponding generic product, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed the following (a or b):
   a. Avodart: 0.5 mg per day (1 capsule per day);

b. Jalyn: 0.5 mg dutasteride/0.4 mg tamsulosin (1 capsule per day).

**Approval duration:**
**Medicaid –** 12 months
**Commercial –** 12 months or duration of request, whichever is less

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Benign Prostatic Hyperplasia** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for brand Avodart or Jalyn, member must use the corresponding generic product, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed (a or b):
   a. Avodart: 0.5 mg per day (1 capsule per day);
   b. Jalyn: 0.5 mg dutasteride/0.4 mg tamsulosin (1 capsule per day).

**Approval duration:**
**Medicaid –** 12 months
**Commercial –** 12 months or duration of request, whichever is less

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
BPH: benign prostatic hyperplasia
FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| doxazosin (Cardura®) | 1 to 8 mg PO once daily | 8 mg/day |
| finasteride (Proscar®) | 5 mg PO once daily | 5 mg/day |
| prazosin (Minipress®) | 2 mg PO twice daily | 9 mg/day |
| tamsulosin (Flomax®) | 0.4 mg PO once daily | 0.8 mg/day |
| terazosin (Hytrin®) | 5 – 10 mg PO once daily | 20 mg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): pregnancy or women of childbearing potential and clinically significant hypersensitivity
- Boxed warning(s): none reported

## V. Dosage and Administration

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Dutasteride (Avodart) | 0.5 mg PO QD | 0.5 mg/day |
| Dutasteride/tamsulosin (Jalyn) | 1 capsule PO QD | 0.5 mg dutasteride and 0.4 mg tamsulosin/day |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| Dutasteride (Avodart) | Capsule: 0.5 mg |
| Dutasteride/tamsulosin (Jalyn) | Capsule: 0.5/0.4 mg |

## VII. References

1. Avodart Drug Monograph. Clinical Pharmacology. Available at: http://www.clinicalpharmacology-ip.com. Accessed February 21, 2022.
2. Avodart Prescribing Information. Somerset, NJ: GlaxoSmithKline; January 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021319s032lbl.pdf. Accessed February 21, 2022.
3. Jalyn Prescribing Information. Somerset, NJ: GlaxoSmithKline; December 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022460Orig1s011lbl.pdf. Accessed February 21, 2022.
4. McVary KT, Roehrborn CG et al. American Urological Association guideline: management of benign prostatic hyperplasia (BPH). Published 2010; reviewed and validity confirmed 2014.
5. Lerner, LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline. Available at: https://www.auanet.org/guidelines/guidelines/benign-prostatic-hyperplasia-(bph)-guideline#x8196. Accessed February 21, 2022.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial and HIM lines of business; split from HIM.PA.39; added Medicaid line of business; Commercial: increased trial from 1 to 2 drugs; references reviewed and updated. | 02.06.17 | 05.18 |
| HIM removed as referenced agents do not require prior authorization for this line of business | 05.29.18 | |
| 2Q 2019 annual review: no significant changes; references reviewed and updated | 02.05.19 | 05.19 |
| 2Q 2020 annual review: no significant changes; references reviewed and updated. | 02.12.20 | 05.20 |
| 2Q 2021 annual review: no significant changes; references reviewed and updated. | 01.21.21 | 05.21 |
| Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less | 09.28.21 | 02.22 |
| 2Q 2022 annual review: added requirement to redirect to generic Avodart or Jalyn; references reviewed and updated. | 02.21.22 | 05.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.