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

Reference Number: PA.CP.PMN.128
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Revision Log

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 benign prostatic hyperplasia (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 PA Health and Wellness® 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 contraindicated or clinically significant adverse effects are experienced;
4. 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: 12 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Benign Prostatic Hyperplasia (must meet all)**:**
1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. 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: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 policy – PA.CP.PMN.53 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, pediatric patients, 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 once daily	0.5 mg/day
Dutasteride/tamsulosin (Jalyn)	1 capsule PO daily	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. Accessed Feb 2019. Available at: http://www.clinicalpharmacology-ip.com.
2. Avodart Prescribing Information. Somerset, NJ: GlaxoSmithKline; September 2014. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dc330e70-a1d3-400b-3aaf-46067e3fd090. Accessed February 5, 2019.
3. Jalyn Prescribing Information. Somerset, NJ: GlaxoSmithKline; November 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=eba8376d-10e0-42fc-9f76-9e7ebf7ff047#section-8.3. Accessed February 5, 2019.
4. McVary KT, Roehrborn CG et al. American Urological Association guideline: management of benign prostatic hyperplasia (BPH). Published 2010; reviewed and validity confirmed 2014. Available at: https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014)#x2513. Accessed February 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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