Clinical Policy: Benign Prostatic Hyperplasia (BPH) Agents
Reference Number: HIM.PA.39
Effective Date: 05/16
Last Review Date:
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

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

Description
Dutasteride (Avodart®) is 5 alpha-reductase inhibitor.

Tadalafil (Cialis®) is a selective phosphodiesterase (PDE) type 5 inhibitor.

FDA approved indication
Avodart is indicated:
- For the treatment of symptomatic benign prostatic hyperplasia (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.

Limitation of use: Avodart is not approved for the prevention of prostate cancer.

Cialis is indicated:
- For the treatment of erectile dysfunction (ED)
- For the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)
- For the treatment of ED and the signs and symptoms of BPH (ED/BPH)

Limitation of use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

I. Initial Approval Criteria

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

1. Diagnosis of benign prostatic hyperplasia (BPH);
2. Member meets one of the following (a or b):
   a. If request is for dutasteride (Avodart), failure of ≥ 2 formulary medications (e.g., alfuzosin, doxazosin, finasteride, prazosin, tamsulosin or terazosin) at up to maximally indicated doses unless all are contraindicated or clinically significant adverse effects are experienced;
   b. If request is for Cialis, member meets the following (i, ii, and iii):

i. Failure of ≥ 2 formulary medications (e.g., alfuzosin, doxazosin, finasteride, prazosin, tamsulosin or terazosin) at up to maximally indicated doses unless all are contraindicated or clinically significant adverse effects are experienced;
ii. Failure of dutasteride (Avodart) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced *(Note: dutasteride requires a prior authorization)*;
iii. Failure of Rapaflo at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;

3. Dose does not exceed:
   a. Dutasteride (Avodart): 0.5 mg per day (1 capsule per day);
   b. Cialis: 5 mg per day (1 tablet per day).

Approval duration: 12 months

B. Erectile Dysfunction:
Not covered for this diagnosis – use Stendra

C. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Avodart: 0.5 mg per day (1 capsule per day);
   b. Cialis: 5 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; **or**
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

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 – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
BPH: benign prostatic hyperplasia

ED: erectile dysfunction
FDA: Food and Drug Administration
PDE: phosphodiesterase

V. References

1. Avodart, Cialis Drug Monograph. Clinical Pharmacology. Accessed January 2017. http://www.clinicalpharmacology-ip.com
2. Avodart Prescribing Information. Somerset, NJ: GlaxoSmithKline; April 2013. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021319s028s029lbl.pdf. Accessed January 11, 2017.
3. Rapaflo Prescribing Information. Parsippany, NJ: Watson Pharma, Inc.; July 2013. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022206s012lbl.pdf Accessed January 11, 2017.
4. Cialis Prescribing Information. Indianapolis, IN: Lilly USA, LLC; April 2016. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021368s027lbl.pdf Accessed January 11, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guidelines to new format. Adjusted for flow. Renumbered guideline from HIM.PST.100.5 to HIM.PA.39	05/16	05/16
Clinical changes made to criteria -Added max dose requirement in initial approval and re-auth Non-clinical changes -Converted to new template -References updated	01/17	

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.