SmartPA Criteria Proposal

Drug/Drug Class:	Benign Prostatic Hyperplasia Agents PDL Edit
First Implementation Date:	November 14, 2007
Revised Date:	October 14, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: In adult men, the prostate acts mainly to add fluids to the semen that nourish sperm and protect them against the natural acids in the vagina. Benign prostatic hyperplasia (BPH) is one of the most common diseases in aging men – for most men over age 50. The symptoms are brought on by hyperplastic changes in the prostate, leading to prostatic enlargement. The resulting urinary obstruction increases outflow resistance and results in a detrusor muscle response. These participants often present with bothersome lower urinary tract symptoms, including frequency, nocturia, urgency, and urge incontinence resulting from irritation; and/or symptoms secondary to obstruction, such as difficulty initiating urination, or passing urine, weak stream, involuntary post-void dripping of urine, or a sensation of incomplete bladder emptying. Unless participants have developed bladder outlet obstruction, BPH only requires therapy if symptoms have a significant impact on a participant's quality of life. The agents that are most commonly used to treat the lower urinary tract symptoms associated with BPH are alpha-1 adrenergic antagonists, 5-alpha-reductase inhibitors, anticholinergic agents, and phosphodiesterase-5 inhibitors. In mild to moderate symptomatic participants, an alpha-1 adrenergic antagonist as monotherapy is recommended. In severe symptomatic participants, a combination of an alpha-1 adrenergic antagonist and a 5-alpha-reductase inhibitor is recommended. Alpha-1 adrenergic antagonists work in the lower urinary tract by blocking adrenoreceptors in the prostate to cause smooth muscles to relax and thus improve urine flow rate and reduce BPH symptoms. Selective 5-alpha reductase inhibitors decrease the serum concentration of 5a-dihydrotestosterone (DHT) which stimulates the growth of glandular and stromal cells, increasing prostatic tissue mass.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Alfuzosin • Doxazosin • Dutasteride • Finasteride 5 mg • Tamsulosin • Terazosin	• Avodart® • Cardura® • Cardura® XL • Cialis® 5 mg • Dutasteride/Tamsulosin • Flomax® • Jayln® • Proscar® • Rapaflo® • Silodosin • Tadalafil 5 mg • Uroxatral®

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Benign Prostatic Hyperplasia Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Cialis: documented diagnosis of benign prostatic hyperplasia

Denial Criteria

- Lack of adequate trial on required preferred agents
- For Cialis:
  - Documented diagnosis of erectile dysfunction **OR**
  - Claim history documents use of nitrates or ritonavir therapy in the past 30 days **OR**
  - Documented contraindication to tadalafil:
    - History of MI in the past 90 days
    - History of unstable angina
    - History of NYHA Class II or greater heart failure
    - History of stroke in the past 6 months
    - History of uncontrolled arrhythmias
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
AVODART 0.5 MG CAPSULE	DUTASTERIDE	1 capsule per day
CIALIS 5 MG TABLET	TADALAFIL	1 tablet per day
FLOMAX 0.4 MG CAPSULE	TAMSULOSIN	2 capsules per day
PROSCAR 5 MG TABLET	FINASTERIDE	1 tablet per day
RAPAFLO 4 MG CAPSULE	SILODOSIN	1 capsule per day

RAPAFLO 8 MG CAPSULE	SILODOSIN	1 capsule per day
UROXATRAL 10 MG TABLET	ALFUZOSIN	1 tablet per day

Required Documentation

Laboratory Results: ☐ Progress Notes: ☐
MedWatch Form: ☐ Other: ☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
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4. Evidence-Based Medicine and Fiscal Analysis: "Benign Prostatic Hyperplasia (BPH) Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
5. Evidence-Based Medicine Analysis: "BPH Inhibitors", UMKC-DIC; April 2021.
6. Uroxatral [package insert]. St. Michael, Barbados: Concordia Pharmaceuticals, Inc; May 2020.
7. Proscar [package insert]. Whitehouse Station, NJ: Merck & Co; April 2021.
8. Jalyn [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.
9. Avodart [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2020.
10. Cialis [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2020.
11. Cardura [package insert]. New York, NY: Pfizer; March 2019.
12. Cardura XL [package insert]. New York, NY: Pfizer; February 2017.
13. Flomax [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; January 2019.
14. Rapaflo [package insert]. Madison, NJ; Allergan USA, Inc; December 2020.