

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Benign Prostatic Hyperplasia Agents PDL Edit
<b>First Implementation Date:</b>	November 14, 2007
<b>Proposed Date:</b>	October 17, 2023
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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
	<ul style="list-style-type: none"> <li>Alfuzosin</li> <li>Doxazosin</li> <li>Dutasteride</li> <li>Finasteride 5 mg</li> <li>Tamsulosin</li> <li>Terazosin</li> </ul>	<ul style="list-style-type: none"> <li>Avodart®</li> <li>Cardura®</li> <li>Cardura® XL</li> <li>Cialis® 5 mg</li> <li>Dutasteride/Tamsulosin</li> <li>Entadfi®</li> <li>Flomax®</li> </ul>

	<ul style="list-style-type: none"> <li>• Jalyn®</li> <li>• Proscar®</li> <li>• Rapaflo®</li> <li>• Silodosin</li> <li>• Tadalafil 5 mg</li> <li>• Uroxatral®</li> </ul>
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Type of Criteria: ☐ Increased risk of ADE  
☒ Appropriate Indications

☒ Preferred Drug List  
☐ 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 **and Entadfi**: documented diagnosis of benign prostatic hyperplasia

## Denial Criteria

- Lack of adequate trial on required preferred agents
- For Cialis **and Entadfi**:
  - 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
<b>ENTADFI 5-5 MG CAPSULE</b>	<b>FINASTERIDE AND TADALAFIL</b>	<b>1 capsule per day</b>
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: ☐

SmartPA PDL Proposal Form

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MedWatch Form:

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Other:

☐

## Disposition of Edit

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

## Default Approval Period

1 year

## References

- Evidence-Based Medicine Analysis: "BPH Inhibitors", UMKC-DIC; March 2023.
- Evidence-Based Medicine and Fiscal Analysis: "Benign Prostatic Hyperplasia (BPH) Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- Cunningham, G., & Kadmon, D., (2019). Medical treatment of benign prostatic hyperplasia. In J. Givens (Ed.), *UptoDate*.
- Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206: 806.
- Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part II, surgical evaluation and treatment. J Urol 2021; 206: 818.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.