Pharmacy Medical Policy
Benign Prostatic Hyperplasia - BPH

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Policy Number: 040
BCBSA Reference Number: None

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.
Prior Authorization Information

☐ Prior Authorization
☒ Step Therapy
☐ Quality Care Dosing

Pharmacy Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289
Policy last updated 7/1/2023

Pharmacy (Rx) or Medical (MED) benefit coverage
☒ Rx
☐ MED

To request for coverage: Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration

Policy applies to Commercial Members:
- Managed Care (HMO and POS),
- PPO and Indemnity
- MEDEX with Rx plan
- Managed Major Medical with Custom BCBSMA Formulary
- Comprehensive Managed Major Medical with Custom BCBSMA Formulary
- Managed Blue for Seniors with Custom BCBSMA Formulary

Please refer to the chart below for the formulary status of the medications affected by this policy.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td>Formulary Status</td>
</tr>
<tr>
<td>STEP 1</td>
<td></td>
</tr>
<tr>
<td>• dutasteride</td>
<td>Covered</td>
</tr>
<tr>
<td>• dutasteride/Tamulosin</td>
<td></td>
</tr>
<tr>
<td>• finasteride</td>
<td></td>
</tr>
<tr>
<td>STEP 2</td>
<td></td>
</tr>
<tr>
<td>• Avodart™ (dutasteride)</td>
<td>Prior use of Step 1 Required</td>
</tr>
<tr>
<td>• Entadfi™ (finasteride/tadalafil)</td>
<td></td>
</tr>
<tr>
<td>• Jalyn™ (dutasteride/tamulosin)</td>
<td></td>
</tr>
<tr>
<td>• Proscar® (finasteride)</td>
<td></td>
</tr>
</tbody>
</table>

We cover the benign prostatic hyperplasia (BPH) medications listed in the chart above for new starts* in the following stepped approach.

*New start is defined as no previous paid claim for the requested medication within the past 130 days.

Step 1: Step 1 medications will be covered without prior authorization.

Step 2: Step 2 medications may be covered when one of the following criteria is met:
- There must be evidence of a BCBSMA paid claim by the patient of a step 1 drug within the previous 130 days or previous treatment.
OR

- There must be evidence of a BCBSMA paid claim by the patient of a step 2 drug within the previous 130 days or previous treatment.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We do not cover drugs listed in the above chart unless the above step therapy criteria are met.

- **Prior Authorization Requirements for tadalafil:**

Tadalafil 5 mg or 2.5 mg may be covered when **ALL** of the following criteria are met:

- Diagnosis of BPH,
- **AND**
- 60-day trial of Alpha-1 Adrenergic Blockers (e.g. DOXAZOSIN, GUANETHIDINE, PRAZOSIN, TERAZOSIN),
- **AND**
- Prescribed by a board-eligible or board-certified Urologist,
- **AND**
- 60-day trial of 5-Alpha Reductase Inhibitor (e.g. finasteride or dutasteride) **OR**
- 60-day trial of combination product of 5-Alpha Reductase Inhibitors & Alpha-1 Adrenergic Blockers (e.g. JALYN*, DUTASTEIDE/TAMSULOSIN)

We may cover **Cialis 5 mg** or 2.5 mg with previous use of tadalafil and above criteria was met.

Note: All other strengths are managed through Medical policy 078 (Sexual Dysfunction Diagnosis and Therapy)

*# Non-formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and requires TWO formulary drugs to be tried prior to granting a Formulary Exception (FE).

***Requests based exclusively on the use of samples will not meet coverage criteria for prior authorization. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

**Individual Consideration**
All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289
Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>11/2022</td>
<td>Updated to add Entadfi™ (finasteride/tadalafil) to the policy at step 2.</td>
</tr>
<tr>
<td>7/2022</td>
<td>Clarified Tadalafil requirements.</td>
</tr>
<tr>
<td>9/2019</td>
<td>Updated to revise Step Criteria.</td>
</tr>
<tr>
<td>5/1/2019</td>
<td>Updated to change criteria for tadalafil &amp; require the use of a combo product which is aligned with guidelines.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>6/2016</td>
<td>Updated to add Dutasteride &amp; Dutasteride/Tamulosin to step 1 and to add Cialis 5mg criteria to policy.</td>
</tr>
<tr>
<td>1/2014</td>
<td>Updated ExpressPATH language and remove Blue Value.</td>
</tr>
<tr>
<td>11/2010</td>
<td>Updated to include coverage criteria for new FDA approved medication Jalyn™.</td>
</tr>
<tr>
<td>9/2009</td>
<td>Policy updated to change 180 day look back period to 130 days, update sample language and to remove Medicare Part D criteria from Medical Policy.</td>
</tr>
<tr>
<td>1/1/2008</td>
<td>New policy, effective 1/1/2008, describing covered and non-covered indications.</td>
</tr>
</tbody>
</table>

References

Endnotes

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below: