Benign Prostatic Hyperplasia (BPH) Step Therapy Policy

Policy Number: 5.01.593  Last Review: 7/2017
Origination: 7/2014  Next Review: 7/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for brand name BPH medications when the following criteria are met. The brand name medications affected are:

- Avodart™ (dutasteride capsules – GlaxoSmithKline; generics)
- Jalyn™ (dutasteride/tamsulosin – GlaxoSmithKline; generics)
- Proscar® (finasteride tablets - Merck, generics)

When Policy Topic is covered
A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Step 1: finasteride 5 mg
Step 2: Avodart, dutasteride, Jalyn, dutasteride/tamsulosin, Proscar

Criteria

1. If a patient has previously tried finasteride (brand or generic), then authorization for a Step 2 product may be given.

2. Coverage of a Step 2 drug is not recommended for treatment of male pattern hair loss (MPHL). Avodart 0.5 mg was evaluated in adult men with MPHL (n = 153) in a randomized, double-blind, placebo-controlled, Phase 3 study and was found to statistically significantly increase hair growth (P = 0.0319). Finasteride is the active ingredient in Propecia® (1 mg vs. 5 mg as Proscar), which is indicated for the treatment of male pattern hair loss. However, MPHL is considered a cosmetic use. Coverage is not recommended as cosmetic indications are excluded from coverage in a typical pharmacy benefit.

3. No other exceptions are recommended.

When Policy Topic is not covered
The use of BPH medications is considered investigational for all other indications.

Considerations
Avodart, Jalyn and Proscar require prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and
Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

**Description of Procedure or Service**

5 alpha-reductase inhibitors and alpha1-blockers are the most commonly used therapies in the treatment of symptomatic benign prostatic hyperplasia (BPH). Finasteride and dutasteride are both indicated to improve symptoms, reduce the risk of acute urinary retention, and to reduce the need for BPH-related surgery in men with enlarged prostates. Dutasteride is also indicated for the treatment of symptomatic BPH in men with an enlarged prostate in combination with the alpha1-blocker, tamsulosin. Jalyn is the commercially available product which combines dutasteride and tamsulosin in one capsule for patients who require dual therapy. The same dosage of dutasteride and tamsulosin can be obtained by taking the respective products individually. Finasteride is also indicated to decrease the risk of symptomatic progression of BPH in combination with the alpha1-blocker doxazosin. According to the American Urological Association (AUA) guidelines (2010) for the management of BPH, the combination of any effective alpha1-blocker and a 5 alpha-reductase inhibitor probably has a comparable benefit.

The Enlarged Prostate International Comparator Study (EPICS) was a randomized, double-blind, multicenter, parallel-group trial that compared the efficacy of finasteride (5 mg/day) and dutasteride (0.5 mg/day) over 12 months in 1,630 patients with BPH. There were no statistically significant differences between the treatment groups in the change in prostate volume, symptom improvement, or urinary flow rate.

**Rationale**

**REFERENCES**


**Billing Coding/Physician Documentation Information**

N/A Avodart, Jalyn and Proscar are considered a pharmacy benefit.

**Additional Policy Key Words**

Policy Number: 5.01.593

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Year</th>
<th>Update Information</th>
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<tbody>
<tr>
<td>07/2014</td>
<td>New Policy titled Benign Prostatic Hyperplasia Step Therapy Program</td>
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<tr>
<td>07/2015</td>
<td>Annual Revision – no changes made</td>
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<tr>
<td>07/2016</td>
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