MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy
Benign Prostatic Hyperplasia - BPH

Table of Contents

Policy Number: 040

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #**621B**
- Sexual Dysfunction Diagnosis and Therapy Medical Policy #**078**

Prior Authorization Information

Policy	☒ Prior Authorization ☒ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**10/1/2023**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers 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 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** 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 **Policy does NOT apply to**: • Medicare Advantage			

Summary

This is a comprehensive policy covering step therapy, prior authorization and quantity limit requirements for medications used to treat Benign Prostatic Hyperplasia (BPH).

This policy applies to members utilizing the below medications for the treatment BPH. Coverage of medications listed below that are FDA approved for other indications can be found in the related Medical Polices listed above.

Policy

Step Therapy Requirements

Length of Approval	24 months
Formulary Status	All requests must meet the Step Therapy requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

The step therapy medications:

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
dutasteride	Covered	Covered with no requirements
Dutasteride/tamsulosin	Covered	
finasteride (5mg tablets only)	Covered	
Step 2		
Avodart ™ (dutasteride)	ST	Requires prior use of a step 1 medication OR history of prior use of any step 2 medication within the previous 130 days. See below for prior use criteria.
Entadfi ™ (finasteride/tadalafil)	ST	
Jalyn ™ (dutasteride/tamsulosin)	ST	
Proscar ® (finasteride)	ST	

ST – Step Therapy

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Prior Authorization Requirements

Length of Approval	12 months
Formulary Status	All requests must meet the PA requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior authorization requirements are as follows:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
tadalafil	PA, QCD	Covered if PA criteria below are met
Cialis	NF, PA, QCD	Non-formulary exception and PA criteria apply

QCD - Quality Care Dosing (quantity limits policy #621B); NF – Non-formulary; PA – Prior Authorization

Tadalafil

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

1. Diagnosis of BPH; **AND**
2. Prescribed by a board-eligible or board-certified Urologist; **AND**
3. 60-day trial of an Alpha-1 Adrenergic Blockers (e.g., doxazosin, prazosin, terazosin)**; AND**
4. 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., dutasteride/tamsulosin)

Cialis 5mg or 2.5mg may be covered with previous use of **tadalafil** AND the above criteria is met**.**

NOTE: All other strengths are managed through Medical Policy 078 (Sexual Dysfunction Diagnosis and Therapy).

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;

- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

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

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
9/2023	Reformatted Policy. Updated IC section to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
11/2022	Updated to add Entadfi ™ (finasteride/tadalafil) to the policy at step 2.
7/2022	Clarified Tadalafil requirements.
9/2019	Updated to revise Step Criteria.
5/1/2019	Updated to change criteria for tadalafil & require the use of a combo product which is aligned with guidelines.
6/2017	Updated address for Pharmacy Operations.
6/2016	Updated to add Dutasteride & Dutasteride/Tamulosin to step 1 and to add Cialis 5mg criteria to policy.
1/2014	Updated ExpressPAth language and remove Blue Value.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
11/2010	Updated to include coverage criteria for new FDA approved medication Jalyn™.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
9/2009	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.
1/1/2008	New policy, effective 1/1/2008, describing covered and non-covered indications.

Forms

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

Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. Avodart ® [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007.
2. Proscar ® [package insert]. Whitehouse Station, NJ: Merck & Co. In.; 2007.
3. Jalyn ™ [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2010.
4. Cialis ® [package insert]. Indianapolis, IN: Lilly USA, LLC; 2015.
5. Entadfi ™ [package insert]. Miami, FL: Veru Inc.; 12/2021.