MASSACHUSETTS

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Pharmacy Medical Policy
Topical Testosterone

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Policy Number: 345

BCBSA Reference Number: N/A

Related Policies

- N/A

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	**8/2024**
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 requirements for topical testosterones.

Policy

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 requirements for topical testosterone covered on the formulary are as follows:

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Testosterone Gel 25 mg/2.5gm (1%), 50mg/5gm Packets [FDA approved Generic], 50mg/5gm Gel, 30mg/1.5ml, 1.62% gel pump, 1.62% Gel packets, 10mg (2%) gel pump, 12.5mg/1.25G (1%) gel pump	Covered	Covered with no requirements
Step 2		
AndroGel ® (testosterone gel)	ST	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication within the previous 130 days. See below for prior use criteria.
Natesto ™** (testosterone gel)	NFNC	
Testim ®** (testosterone gel)	NFNC	
Vogelxo ™** (testosterone gel)	NFNC	

ST – Step Therapy; NFNC – Non-formulary / Non-Covered

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.

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
7/2024	Updated to add AGs to be covered under step 1.
9/2023	Reformatted Policy. Updated IC section to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
7/2019	Updated to add Axiron (7/2018 was not coded) & Androgel to step 2.
2/2019	Updated to add Generic Androgel and a generic 10% gel pump to step 1.
9/2018	Updated to add a new Generic to step one and clarify Non-covered requirements.
1/2018	Updated to add generic Testosterone Soln and to move Axiron to step 2 of policy
6/2017	Updated address for Pharmacy Operations.
10/2015	Updated to add FDA approved Generic.
4/2015	Added Natesto™ to Step 2.
1/2015	Move Testim & its Authorized Generic to non-covered.

10/2014	Added AndroGel®, Androderm® & Axiron® to Step 1. Removed Step 3 and made policy a 2 step policy.
8/2014	Updated to include generics.
1/2014	Updated ExpressPAth Language and removed Blue Value.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/1/2012	New policy, effective 1/1/2012, 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. Androderm® [package insert]. Morristown, NJ: Watson Pharma, Inc.; 2010.
2. AndroGel® [package insert]. North Chicago, IL: Abbott Laboratories; 2011.
3. Axiron® [package insert]. Indianapolis, IN: Eli Lilly and Company ; 2011.
4. Fortesta™ [package insert]. Chadds Ford, PA: Endo Pharmaceuticals; 2011.
5. Testim® [package insert]. Malvem, PA: Auxilium Pharmaceuticals, Inc. 2009.
6. Vogelxo™ [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc; 2014
7. Naesto™ [package insert]. Malvern, PA: Endo Pharmaceuticals Inc ; 11/2014