Pharmacy Medical Policy
Topical Testosterone

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Policy Number: 345
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 (Rx) or Medical (MED) benefit coverage | ☒ Rx | ☐ MED |

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

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 last updated 7/1/2023

Pharmacy Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289

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Please refer to the chart below for the formulary and step 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>
</tbody>
</table>

**STEP 1**

| Testosterone Gel 25 mg/2.5gm, 50mg/5gm Packets [FDA approved Generic], 50mg/5gm Gel, 30mg/1.5ml, 1.62% gel pump, 1.62% Gel packets, 10% gel pump | Covered |
| Androderm® (testosterone patch) |

**STEP 2**

| AndroGel® (testosterone gel) | Prior use of Step 1 Required |

| Fortesta™ (testosterone gel) |
| Natesto™ (testosterone gel) |
| Testim® (testosterone gel) |

| Testosterone gel 50 mg/5 g (5 g)** (Authorized Brand of Testim®)** [Customarily referred to as an authorized Generic] | |
| Testosterone gel 12.5 mg/actuation (1%) (75 g)** & 50mg/5GM Gel Packet** (Authorized Brand of Vogelxo™)** [Customarily referred to as an authorized Generic] | |
| Vogelxo™ (testosterone gel) |

**Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and criteria below are met.

We may cover the Topical Testosterone medications listed in the chart above for new starts* in the following stepped approach.¹

*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 are met:
- There must be evidence of a BCBSMA paid claim by the patient of a step 1 medication within the previous 130 days or previous treatment.
  OR
- There must be evidence of a BCBSMA paid claim by the patient of the step 2 medication within the previous 130 days or previous treatment.

NOTE: If a Provider submits a request and BCBSMA issues an approval for a step medication, the authorization will be granted for up to two (2) years. If the Member has claims history verifying a fill of a formulary step 1 or formulary step 2 medication within the past 130 days, and no break in coverage, then formulary step 2 medications will continue to pay at point of sale. If the Member has claims history verifying a fill of a formulary step 2 or formulary step 3 medication within the past 130 days, and no break in coverage, then formulary step 3 medications will continue to pay at point of sale. Non-formulary (not covered) medications within a step policy will not have any automation and a paper, electronic or phone call is required.

** 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).

Note:*Exception requests based exclusively on the use of samples will not meet coverage criteria for non-formulary medications. Additional clinical information demonstrating medical necessity of the non-formulary 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.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>7/2019</td>
<td>Updated to add Axiron (7/2018 was not coded) &amp; Androgel to step 2.</td>
</tr>
<tr>
<td>2/2019</td>
<td>Updated to add Generic Androgel and a generic 10% gel pump to step 1.</td>
</tr>
<tr>
<td>9/2018</td>
<td>Updated to add a new Generic to step one and clarify Non-covered requiremnts.</td>
</tr>
<tr>
<td>1/2018</td>
<td>Updated to add generic Testosterone Soln and to move Axiron to step 2 of policy</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>10/2015</td>
<td>Updated to add FDA approved Generic.</td>
</tr>
<tr>
<td>4/2015</td>
<td>Added Natesto™ to Step 2.</td>
</tr>
<tr>
<td>1/2015</td>
<td>Move Testim &amp; its Authorized Generic to non-covered.</td>
</tr>
</tbody>
</table>
Added AndroGel®, Androderm® & Axiron® to Step 1. Removed Step 3 and made policy a 2 step policy.

Updated to include generics.

Updated ExpressPAth Language and removed Blue Value.

Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.

New policy, effective 1/1/2012, describing covered and non-covered indications.

References

Endnotes
1. Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 9/13/2011.

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