



# MASSACHUSETTS

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## Pharmacy Medical Policy Overactive Bladder Medications

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**Policy Number: 170**

BCBSA Reference Number: N/A

### Related Policies

- N/A

### Prior Authorization Information

Policy	<input type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Step Therapy <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Administrative	Reviewing Department  Policy Effective Date	<b>Pharmacy Operations:</b> Tel: 1-800-366-7778 Fax: 1-800-583-6289  <b>10/1/2023</b>
Pharmacy (Rx) or Medical (MED) benefit coverage	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> MED	<b>To request for coverage:</b> Providers may call, fax, or mail the attached form ( <a href="#">Formulary Exception/Prior Authorization form</a> ) to the address below.	
<b>Policy applies to Commercial Members:</b> <ul style="list-style-type: none"> <li>• Managed Care (HMO and POS),</li> <li>• PPO and Indemnity</li> <li>• MEDEX with Rx plan</li> <li>• Managed Major Medical with Custom BCBSMA Formulary</li> <li>• Comprehensive Managed Major Medical with Custom BCBSMA Formulary</li> <li>• Managed Blue for Seniors with Custom BCBSMA Formulary</li> </ul> <b>Policy does NOT apply to:</b> <ul style="list-style-type: none"> <li>• Medicare Advantage</li> </ul>		<b>Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department</b> 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289  <b>Individual Consideration for the atypical patient:</b> Policy for requests that do not meet clinical criteria of this policy, see section labeled <a href="#">Individual Consideration</a>	

### Summary

This is a comprehensive policy covering step therapy requirements for medications used to treat overactive bladder.

## Policy

<b>Length of Approval</b>	24 months
<b>Formulary Status</b>	All requests must meet the Step Therapy requirement and for non-covered medications, the member <b>must</b> also have had a previous treatment failure with, or contraindication to, <b>at least two</b> covered formulary alternatives when available. See section on <a href="#">individual consideration</a> for more information if you require an exception to any of these criteria requirements for an atypical patient.
<b>Member cost share consideration</b>	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:

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
<b>Step 1</b>		
darifenacin ER	Covered	Covered with no requirements
fesoterodine	Covered	
oxybutynin	Covered	
oxybutynin ER	Covered	
solifenacin	Covered	
tolterodine	Covered	
tolterodine ER	Covered	
tropium	Covered	
tropium XR	Covered	
<b>Step 2</b>		
Myrbetriq™ (mirabegron)	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.
Gemtesa® (vibegron)	ST	
<b>Step 3</b>		
Detrol® (tolterodine)	NFNC, ST	Requires prior use of ONE step 1 medication <b>AND</b> ONE step 2 medication OR history of prior use of a step 3 medication within the previous 130 days.  See below for prior use criteria.
Detrol LA® (tolterodine)	NFNC, ST	
Ditropan® (oxybutynin)	NFNC, ST	
Ditropan® XL (oxybutynin)	NFNC, ST	
Gelnique® (oxybutynin)	NFNC, ST	
Oxytro I® (oxybutynin)##	NFNC, ST	
Toviaz™ (fesoterodine fumarate)	NFNC, ST	
Vesicare® (solifenacin succinate)	NFNC, ST	

**ST – Step Therapy; NFNC – Non-formulary/Not-covered**

**## By benefit design [contract] Oxytrol® OTC Patch is excluded from coverage as it is available without a prescription**

## 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
9/2023	Reformatted Policy. Updated IC section to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
11/2022	Updated to add Generic Toviaz and clarified some coding.
4/2021	Update to add Gemtesa to step 2.
1/2021	Update to add Vesicare to step 3.
9/2019	Updated to revise Step Criteria.
7/2019	Updated to add Solifenacin to step 1.
10/2017	Updated to add Myrbetriq™ to Step2 of Policy.
6/2017	Updated address for Pharmacy Operations.
10/2016	Added Darifenacin ER to step 1 and removed gender reference.
3/2014	Added Tolterodine ER to step 1.
1/2014	Updated to limit Oxytrol <sup>®</sup> prescription coverage to males because an FDA approved product, <u>Oxytrol<sup>®</sup> for Women</u> is available for females without a prescription. Updated ExpressPAth language and remove Blue Value.
3/2013	Updated to include coverage for new FDA approved medications tolterodine, trospium and trospium XR.
9/2012	Updated to include coverage for new FDA approved medication Myrbetriq™
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Updated to include Gelnique <sup>®</sup> and Oxytrol <sup>®</sup> as Step 3 medications.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
1/1/2010	New policy, effective 1/1/2010, 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. Detrol<sup>®</sup> LA [package insert]. New York, NY: Pfizer Labs; August 2012.
2. Ditropan<sup>®</sup> XL [package insert]. Vacaville, CA: Alza Corporation; 2009.
3. Enablex<sup>®</sup> [package insert]. Cincinnati, Ohio: Procter & Gamble Pharmaceuticals; 2008.
4. Sanctura<sup>®</sup> XR [package insert]. Irvine, CA: Alelrgan, Inc.; 2007.
5. Sanctura<sup>®</sup> [package insert]. Irvine, CA: Alelrgan, Inc.; July 2012.
6. Toviaz<sup>™</sup> [package insert]. New York, NY: Pfizer Labs; 2008.
7. VESicare [package insert]. Deerfield, IL: Astellas Pharma Technologies; 2008.
8. Gelnique<sup>®</sup> [package insert]. Morristown, NJ: Watson Pharma, Inc., 2011.
9. Oxytrol<sup>®</sup> [package insert]. Morristown, NJ: Watson Pharma, Inc., 2010.
10. Myrbetriq<sup>™</sup> [package insert]. Northbrook, IL: Astellas Pharma Technologies; 2012.
11. Oxytrol<sup>®</sup> for Women [Product Brochure]. MSD Consumer Care, 2013
12. Gemtesa<sup>®</sup> [package insert]. Irvine, CA: Urovant Sciences, Inc.; Jan 2021.