



# MASSACHUSETTS

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## Pharmacy Medical Policy Methotrexate Step Therapy

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**Policy Number: 840**

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 type="checkbox"/> Quantity Limit <input type="checkbox"/> Administrative	Reviewing Department	<b>Pharmacy Operations:</b> Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	<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 methotrexate.

Otrexup and Rasuvo both contain methotrexate in various strengths in an injectable form and are U.S. Food and Drug Administration (FDA) approved for the treatment of patients with severe, active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and severe, recalcitrant, disabling psoriasis. Typically, in these inflammatory conditions, methotrexate is first initiated orally and then could potentially be converted to an injectable form of methotrexate. Otrexup and Rasuvo provide an auto-injectable option for patients to use as an alternative to generic forms of injectable methotrexate. The generic formulations are equally as effective and are available at a fraction of the cost of the auto-injectable options.

## 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>		
Methotrexate (oral)	Covered	Covered with no requirements
Methotrexate sodium (injection)	Covered	
<b>Step 2</b>		
Otrexup <sup>®</sup> (methotrexate)	ST	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication in this table within the previous 130 days.  See below for prior use criteria.
Rasuvo <sup>®</sup> (methotrexate)	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.

## 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.
1/1/2022	Implement new step policy for Otrexup and Rasuvo.

## 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. Otrexup® [package insert]. Ewing, NJ: Antares Pharma, Inc.: 11/2020.
2. Rasuvo® [package insert]. Chicago, IL: Medexus Pharma Inc: 3/2020.