MASSACHUSETTS

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

Pharmacy Medical Policy
Multiple Sclerosis Prior Auth and Step Policy

Table of Contents

Policy Number: 839

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #**621B**
- Medical Utilization Management (MED UM) & Pharmacy Prior Authorization Policy #**033**
- Immune Modulating Drugs Policy #**004**

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	**11/1/2023**
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 Multiple Sclerosis.

This policy applies to members utilizing the below medications for the treatment of Multiple Sclerosis. 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. For drugs that are 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.

Step therapy requirements apply to the following medications for Multiple Sclerosis (MS):

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
dimethyl fumarate	Covered	Covered with no requirements.
fingolimod capsules	Covered	
glatiramer	Covered, *QCD	
Glatopa ® (glatiramer)	Covered, *QCD	
teriflunomide	Covered	
Step 2		
Avonex ® (interferon beta-1a)	ST, *QCD	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.
Betaseron ® (interferon beta-1b)	ST, *QCD	
Kesimpta ® (ofatumumab)	ST	
Plegridy ® (peginterferon beta-1a)	ST, *QCD	
Rebif ® (interferon beta-1a)	ST, *QCD	
Step 3		
Bafiertam ® (monomethyl fumarate)	NFNC, ST	Requires prior use of TWO step 2 medications OR history of prior use of a step 3 medication in this table within the previous 130 days. See below for prior use criteria.
Copaxone ® (glatiramer)	NFNC, ST, QCD	
Extavia ® (interferon beta-1b)	NFNC, ST, QCD	
Ponvory ™ (ponesimod)	NFNC, ST, QCD	
Tascenso ODT ™ (fingolimod)	NFNC, ST	
Tecfidera ® (dimethyl fumarate)	NFNC, ST	

QCD - Quality Care Dosing (quantity limits policy #621B); 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.

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 is required for the following medications for treatment of Multiple Sclerosis:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Aubagio ® (teriflunomide)	PA	PA Required
Gilenya ® (fingolimod)	PA	PA Required
Mavenclad ® (cladribine)	PA	PA Required
Mayzent ® (siponimod)	PA	PA Required
Vumerity ™ (diroximel fumarate)	PA, QCD	PA Required
Zeposia ® (ozanimod)	PA	PA Required
Lemtrada ® (alemtuzumab)	NFNC, PA	Prior authorization required. See related policy # 033 for criteria. Covered ONLY under the Medical Benefit

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

Aubagio ®

Aubagio (teriflunomide) may be covered when **ALL** of the following criteria are met:

1. Confirmed diagnosis of relapsing forms of multiple sclerosis (MS) – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive; **AND**
2. Age 18 years or older; **AND**
3. The medication is prescribed by a board-certified or board eligible Neurologist; **AND**
4. Previous trial of teriflunomide or clinical rational for being unable to use.

Gilenya ®

Gilenya (fingolimod) may be covered when **ALL** of the following criteria are met:

1. Confirmed diagnosis of relapsing forms of multiple sclerosis (MS) – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive; **AND**
2. Age 10 years or older; **AND**
3. The medication is prescribed by a board-certified or board eligible Neurologist.

Mavenclad ®

1. Confirmed diagnosis of relapsing forms of multiple sclerosis (MS) – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; **AND**

2. Age 18 years or older; **AND**

3. The medication is prescribed by a board-certified or board eligible Neurologist; **AND**

4. Previous trial of ONE (1) of the following medications: Aubagio, Avonex, Betaseron, dimethyl fumarate, fingolimod, Gilenya, glatiramer, Glatopa, Kesimpta, Mayzent, Plegridy, Rebif, teriflunomide, or Vumerity.

Mayzent ®, Vumerity ™, and Zeposia ®

Mayzent (siponimod), **Vumerity** (diroximel fumarate) or **Zeposia** (ozanimod) may be covered when **ALL** of the following criteria are met:

1. Confirmed diagnosis of relapsing forms of multiple sclerosis (MS) – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; **AND**

2. Age 18 years or older; **AND**

3. The medication is prescribed by a board-certified or board eligible Neurologist.

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
11/2023	Reformatted Policy.
9/2023	Reformatted Policy. Updated IC section to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
4/2023	Add teriflunomide to the policy at Step 1 and update Aubagio criteria to include teriflunomide.
1/2023	Updated Policy name with addition of Prior Auth required for Aubagio ®, Gilenya ®, Mavenclad ®, Mayzent ®, Vumerity ™, and Zeposia ®.
8/2022	Updated to add Tascenso ODT ™ to step 3 of the policy.
1/1/2022	Implement new step policy for Multiple Sclerosis.

Forms

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

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. Aubagio ® [package insert]. Cambridge, MA: Genzyme Corporation.: 10/2021.
2. Zeposia ® [package insert]. Summit, NJ: Celgene Corporation: 6/2021.
3. Avonex ® [package insert]. Cambridge, MA: Biogen Inc.: 12/2020.
4. Bafiertam ™ [package insert]. High Point, NC: Banner Life Sciences LLC.: 4/2020.
5. Betaseron ® [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.: 3/2021.
6. Gilenya ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.: 7/2021.
7. Kesimpta ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.: 9/2021.
8. Mavenclad ® [package insert]. Rockland, MA: EMD Serono, Inc.: 4/2019.

9. Mayzent ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.: 7/2021.
10. Plegridy ® [package insert]. Cambridge, MA: Biogen Inc.: 6/2021.
11. Rebif ® [package insert]. Rockland, MA: EMD Serono, Inc.: 8/2021.
12. Zeposia ® [package insert]. Summit, NJ: Celgene Corporation: 6/2021.
13. Copaxone ® [package insert]. Parsippany, NJ: Teva Neuroscience, Inc: 7/2020.
14. Extavia ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.: 9/2021.
15. Tecfidera ® [package insert]. Cambridge, MA: Biogen Inc.: 6/2021
16. Ponvory ™ [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.: 4/2021
17. Vumerity ™ [package insert]. Cambridge, MA: Biogen Inc.: 1/2021
18. Tascenso ™ [package insert]. San Jose, CA: Handa Neuroscience, LL.: 12/2021