Pharmacy Medical Policy
Multiple Sclerosis Prior Auth and Step Policy

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Policy Number: 839
BCBSA Reference Number: None

Related Policies
- Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy #621A
- Policy 033 – Tysabri criteria

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 Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289
Policy last updated 7/1/2023

Pharmacy (Rx) or Medical (MED) benefit coverage
☒ Rx
☐ MED

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 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

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Standard Formulary for Multiple Sclerosis Step Chart

<table>
<thead>
<tr>
<th>STEP 1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>dimethyl fumarate</td>
<td>Covered</td>
</tr>
<tr>
<td>Fingolimod capsules</td>
<td></td>
</tr>
<tr>
<td>glatiramer</td>
<td></td>
</tr>
<tr>
<td>Glatopa ® (glatiramer)</td>
<td></td>
</tr>
<tr>
<td>teriflunomide</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STEP 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Avonex ® (interferon beta-1a)</td>
<td>Prior use of one Step 1 Required</td>
</tr>
<tr>
<td>Betaseron ® (interferon beta-1b)</td>
<td></td>
</tr>
<tr>
<td>Kesimpta ® (ofatumumab)</td>
<td></td>
</tr>
<tr>
<td>Plegridy ® (peginterferon beta-1a)</td>
<td></td>
</tr>
<tr>
<td>Rebif ® (interferon beta-1a)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STEP 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bafiertam ®# (monomethyl fumarate)</td>
<td>Requires prior use of two step 2 medications.</td>
</tr>
<tr>
<td>Copaxone ®# (glatiramer)</td>
<td></td>
</tr>
<tr>
<td>Extavia ®# (interferon beta-1b)</td>
<td></td>
</tr>
<tr>
<td>Ponvory ™# (ponesimod)</td>
<td></td>
</tr>
<tr>
<td>Tascenso ODT ™# (fingolimod)</td>
<td></td>
</tr>
<tr>
<td>Tecfidera ®# (dimethyl fumarate)</td>
<td></td>
</tr>
</tbody>
</table>

*For non-formulary/non-covered medications, requests must meet criteria above and the member must have had a previous treatment failure with or a contraindication to two covered formulary step 2 alternatives when available.
Prior Authorization (PA) Criteria for Multiple Sclerosis

Standard Formulary for Prior Authorization for Multiple Sclerosis

<table>
<thead>
<tr>
<th>Drug</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aubagio ® (teriflunomide)</td>
<td>Pa Required</td>
</tr>
<tr>
<td>Gilenya ® (fingolimod)</td>
<td></td>
</tr>
<tr>
<td>Mavenclad ® (cladribine)</td>
<td></td>
</tr>
<tr>
<td>Mayzent ® (siponimod)</td>
<td></td>
</tr>
<tr>
<td>Vumerity ™ (diroximel fumarate)</td>
<td></td>
</tr>
<tr>
<td>Zeposia ® (ozanimod)</td>
<td></td>
</tr>
</tbody>
</table>

We may cover Mayzent ® (siponimod), Vumerity ™ (diroximel fumarate) or Zeposia ® (ozanimod) when ALL the following criteria are met:

- Patient has a confirmed diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, AND
- The drug is prescribed by a board-certified or board eligible Neurologist, AND
- Age is greater than or equal to 18 years of age.

We may cover Aubagio ® (teriflunomide) when ALL the following criteria are met:

- Patient has a confirmed diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, AND
- The drug is prescribed by a board-certified or board eligible Neurologist, AND
- Age is greater than or equal to 18 years of age, AND
- Must have a trial of teriflunomide or clinical rational for skipping this criterion.

We may cover Gilenya ® (fingolimod) when ALL the following criteria are met:

- Patient has a confirmed diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, AND
- The drug is prescribed by a board-certified or board eligible Neurologist, AND
- Age is greater than or equal to 10 years of age.

**Note:** If approved the Prior Authorization will be granted for up to one (1) year.

We may cover Mavenclad ® (cladribine) when ALL the following criteria are met:

- Patient has a confirmed diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, AND
- The drug is prescribed by a board-certified or board eligible Neurologist, AND
- Age is greater than or equal to 18 years of age, AND
- There has been previous treatment failure with ONE (1) following Drugs: Aubagio, Avonex, Betaseron, dimethyl fumarate, fingolimod, Gilenya, glatiramer, Glatopa, Kesimpt, Mayzent, Plegridy, Rebif, teriflunomide, or Vumerity

**Note:** If approved the Prior Authorization will be granted for up to one (1) year.
**Step Therapy Criteria for Multiple Sclerosis**

We may cover the following Multiple Sclerosis medications listed in the Step chart above for new starts* in the following stepped approach:

*New start is defined as no previous paid claim for the requested medication within the past 130 days.

**Step 1:** Formulary step 1 medications will be covered without prior authorization.

**Step 2:** Formulary step 2 medications may be covered when one of the following criteria is met:
- There must be evidence of a BCBSMA paid claims in the Step 1 drug class within the previous 130 days or previous treatment.

**OR**
- There must be evidence of a BCBSMA paid claim by the patient of a Step 2 drug within the previous 130 days or previous treatment.

**Step 3:** Step 3# medications may be covered when the following criteria is met:
- There must be evidence of BCBSMA paid claims by the patient of prior use of two (2) step 2 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 3 drug within the previous 130 days or previous treatment. If the Medication is Not Covered/Non-formulary the drug needs to meet requirements for a Formulary Exception for continued coverage.: 

**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.

For non-formulary/non-covered medications, requests must meet criteria above and the member must have had a previous treatment failure with or a contraindication to two covered formulary alternatives when available.

We do not cover the medications listed above for other conditions not listed above.

**CPT Codes / HCPCS Codes / ICD-9 Codes**

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
CPT Codes

There is no specific CPT code for this service.

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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>4/2023</td>
<td>Add teriflunomide to the policy at Step 1 and update Aubagio criteria to include teriflunomide.</td>
</tr>
<tr>
<td>1/2023</td>
<td>Updated Policy name with addition of Prior Auth required for Aubagio®, Gilenya®, Mavenclad®, Mayzent®, Vumerity™, and Zeposia®.</td>
</tr>
<tr>
<td>8/2022</td>
<td>Updated to add Tascenso ODT™ to step 3 of the policy.</td>
</tr>
<tr>
<td>1/1/2022</td>
<td>Implement new step policy for Multiple Sclerosis.</td>
</tr>
</tbody>
</table>

References

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