Multiple Sclerosis Agents
- Aubagio® (teriflunomide)
- Bafiertam (monomethyl fumarate)
- Gilenya® (fingolimod)
- Mayzent® (siponimod)
- Tecfidera® (dimethyl fumarate)
- Vumerity® (diroximel fumarate)

Effective 01/01/2022

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ MassHealth</td>
<td>☑ Prior Authorization</td>
</tr>
<tr>
<td>☑ MassHealth (PUF)</td>
<td>☑ Quantity Limit</td>
</tr>
<tr>
<td>☐ Commercial/Exchange</td>
<td>☐ Step Therapy</td>
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<table>
<thead>
<tr>
<th>Benefit</th>
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<tr>
<td>☑ Pharmacy Benefit</td>
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<td>☐ Medical Benefit (NLX)</td>
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</table>

Specialty Limitations
These medications have been designated specialty and must be filled at a contracted specialty pharmacy.

<table>
<thead>
<tr>
<th>Contact Information</th>
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<tbody>
<tr>
<td>Specialty Medications</td>
</tr>
<tr>
<td>All Plans</td>
</tr>
<tr>
<td>Phone: 866-814-5506</td>
</tr>
<tr>
<td>Fax: 866-249-6155</td>
</tr>
</tbody>
</table>

| Non-Specialty Medications                 |
| MassHealth                                |
| Phone: 877-433-7643                       |
| Fax: 866-255-7569                        |

| Commercial                                  |
| Phone: 800-294-5979                       |
| Fax: 888-836-0730                        |

| Exchange                                    |
| Phone: 855-582-2022                       |
| Fax: 855-245-2134                        |

Medical Specialty Medications (NLX)
All Plans
Phone: 844-345-2803
Fax: 844-851-0882

Exceptions
N/A

Overview
FDA approved indications:
Clinically Isolated Syndrome (CIS): Aubagio®, Bafiertam®, Gilenya®, Mayzent®, Ponvory®, dimethyl fumarate, Vumerity®
Relapse-remitting MS (RRMS) and Active Secondary-progressive MS (SPMS)*: Aubagio®, Bafiertam®, Gilenya®, Mavenclad®, Mayzent®, Ponvory®, dimethyl fumarate, Vumerity®

<table>
<thead>
<tr>
<th>No PA</th>
<th>PA required</th>
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</thead>
<tbody>
<tr>
<td>Copaxone® (glatiramer)§</td>
<td>Aubagio® (teriflunomide)</td>
</tr>
<tr>
<td></td>
<td>Bafiertam® (monomethyl fumarate)</td>
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<tr>
<td></td>
<td>Gilenya® (fingolimod)§</td>
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<td></td>
<td>Mavenclad® (cladribine tablet)</td>
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<tr>
<td></td>
<td>Mayzent® (siponimod)</td>
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<tr>
<td></td>
<td>Ponvory® (ponesimod)</td>
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<tr>
<td></td>
<td>Tecfidera® (dimethyl fumarate) § PD *</td>
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<tr>
<td></td>
<td>Vumerity® (diroximel fumarate)</td>
</tr>
</tbody>
</table>

§ Brand Preferred over generic equivalents. A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for Tecfidera® (dimethyl fumarate) a trial with a preferred agent is not required prior to approval of a non-preferred agent.

*A-rated generic available. Both brand and A-rated generic require PA.

**Coverage Guidelines**

Authorizations requests will be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

**Aubagio®** (teriflunomide), **Gilenya®** (fingolimod) § **and Tecfidera®** (dimethyl fumarate) §

Prescriber provides documentation of **ALL** of the following:

1. The member has a diagnosis of Clinically Isolated Syndrome (CIS) OR Relapse-remitting Multiple Sclerosis (RRMS) OR Active Secondary-Progressive MS (SPMS)*
2. The prescriber is a neurologist or medication is being prescribed in consultation with a neurologist
3. **ONE** of the following:
   a. For Aubagio® and Gilenya®: quantity requested is ≤ 1 unit/day
   b. For dimethyl fumarate: quantity requested is ≤ 2 tablets/day
4. For Gilenya®, **ONE** of the following (weight may be taken over the phone if not documented on the PA request):
   a. For Gilenya® 0.5 mg: weight ≥40 kg
   b. For Gilenya® 0.25 mg: weight <40 kg

**Bafiertam** (monomethyl fumarate)

Prescriber provides documentation of **ALL** of the following:

1. The member has a diagnosis of Clinically Isolated Syndrome (CIS) OR Relapse-remitting Multiple Sclerosis (RRMS) OR Active Secondary-Progressive MS (SPMS)*
2. The prescriber is a neurologist or medication is being prescribed in consultation with a neurologist
3. Provider documents medical necessity for use of Bafiertam instead of dimethyl fumarate AND Vumerity (diroximel fumarate)
4. Quantity requested is ≤ 4 capsules/day

**Mavenclad®** (cladribine tablet)

Prescriber provides documentation of **ALL** of the following:

1. The member has a diagnosis of Relapse-remitting Multiple Sclerosis (RRMS) OR Active Secondary-Progressive MS (SPMS)*
2. Prescriber is a neurologist or consult notes from a neurology office are provided
3. Paid claims or physician attestation of inadequate response or adverse reaction to **THREE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents:
   a. Aubagio® (teriflunomide)
   b. Gilenya® (fingolimod) or Mayzent® (siponimod)
   c. glatiramer acetate therapy
   d. interferon therapy
   e. Ocrevus® (ocrelizumab)
f. dimethyl fumarate or Vumerity®
g. Tysabri® (natalizumab)

4. Requested dose is 3.5 mg/kg divided into two yearly treatment courses (1.75 mg/kg per course)

**Mayzent®** (siponimod)
Prescriber provides documentation of **ALL** of the following:
1. The member has a diagnosis of Clinically Isolated Syndrome (CIS) OR Relapse-remitting Multiple Sclerosis (RRMS) OR Active Secondary-Progressive MS (SPMS)*
2. The prescriber is a neurologist or medication is being prescribed in consultation with a neurologist
3. Provider documents medical necessity for use of Mayzent instead of Gilenya
4. Paid claim or physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents:
   a. Aubagio® (teriflunomide)
   b. glatiramer acetate therapy
   c. interferon therapy
   d. Ocrevus® (ocrelizumab)
   e. Tecfidera® (dimethyl fumarate) or Vumerity® (diroximel fumarate)
5. Genetic testing for CYP2C9 genotype showing the member does NOT have a CYP2C9 *3/*3 genotype
6. Requested dose is appropriate based on the CYP2C9 genotype‡

**Vumerity®** (diroximel fumarate)
1. The member has a diagnosis of Clinically Isolated Syndrome (CIS) OR Relapse-remitting Multiple Sclerosis (RRMS) OR Active Secondary-Progressive MS (SPMS)*
2. The prescriber is a neurologist or medication is being prescribed in consultation with a neurologist
3. Provider documents medical necessity for use of Vumerity instead of dimethyl fumarate
4. Quantity requested is ≤ 4 capsules/day

**Ponvory®** (ponesimod)
Prescriber provides documentation of **ALL** of the following:
1. The member has a diagnosis of Clinically Isolated Syndrome (CIS) OR Relapse-remitting Multiple Sclerosis (RRMS) OR Active Secondary-Progressive MS (SPMS)*
2. The prescriber is a neurologist or medication is being prescribed in consultation with a neurologist
3. Paid claim or physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents:
   a. Aubagio® (teriflunomide)
   b. glatiramer acetate therapy
   c. interferon therapy
   d. Ocrevus® (ocrelizumab)
   e. Tecfidera® (dimethyl fumarate) or Vumerity® (diroximel fumarate)
4. Quantity requested is ≤ 1 unit/day

*For requests that document SPMS, active disease must be confirmed.

**§Brand preferred over generic equivalent:**

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

- dimethyl fumarate
- fingolimod
- Glatopa
- glatiramer acetate

**Continuation of Therapy**

- For RRMS: Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.
- For SPMS: Reauthorization requires physician attestation of active disease, continuation of therapy and positive response to therapy.
- For CIS: Reauthorization will be evaluated on a case by case basis

**Limitations**

1. Initial authorizations and reauthorizations will be granted for 12 months
2. Reauthorizations for Mavenclad beyond two years of therapy will be denied.
3. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity Limits</th>
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<tbody>
<tr>
<td>Copaxone</td>
<td>12 syringes per 28 days</td>
</tr>
<tr>
<td>Aubagio® (teriflunomide)</td>
<td>30 capsules per 30 days</td>
</tr>
<tr>
<td>Bafiertam (monomethyl fumarate)</td>
<td>120 capsules per 30 days</td>
</tr>
<tr>
<td>Gilenya® (fingolimod)§</td>
<td>30 capsules per 30 days</td>
</tr>
<tr>
<td>Mayzent® (siponimod) 2mg capsule</td>
<td>30 tablets per 30 days</td>
</tr>
<tr>
<td>Mayzent® (siponimod) 0.25mg capsules</td>
<td>150 tablets per 30 days</td>
</tr>
<tr>
<td>Ponvory® (ponesimod)</td>
<td>30 capsules per 30 days</td>
</tr>
<tr>
<td>Tecfidera® (dimethyl fumarate) § PD</td>
<td>60 tablets per 30 days</td>
</tr>
<tr>
<td>Vumerity (diroximel fumarate)</td>
<td>120 capsules per 30 days</td>
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**References**


**Review History**

04/25/2016 – Reviewed
04/24/2017 – Reviewed
04/17/2019 – Reviewed in P&T Meeting
10/06/2020 – Effective 1/1/21 Updated to be in compliance with the Masshealth partial unified formulary requirements
05/19/2021 – Reviewed and Updated per MH UPPL; Vumerity added as an acceptable trial for certain agents (Mayzent, Zeposia). Mayzent and Zeposia criteria updated to have medical necessary use of Gilenya and previous use of ONE other medication. Verbiage changes for “Prescriber is a neurologist or consult notes from a neurology office are provided”. Effective 07/01/2021
11/17/2021 – Reviewed and Updated; Updated to include 2 new agents Ponvory and Mavenclad. Aubagio will be preferred. Matched criteria to MH UPPL for effective 1/1/22

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.