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

Effective 07/01/2021

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☒ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
<th>☒ Quantity Limit</th>
<th>☐ Step Therapy</th>
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<tbody>
<tr>
<td>Benefit</td>
<td>☒ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
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<td>Specialty Limitations</td>
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<td>These medications have been designated specialty and must be filled at a contracted specialty pharmacy.</td>
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<td>Contact Information</td>
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<tr>
<td>Specialty Medications</td>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
<td>Fax: 866-249-6155</td>
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<td>Non-Specialty Medications</td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
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<tr>
<td></td>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<td></td>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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<tr>
<td>Medical Specialty Medications (NLX)</td>
<td>All Plans</td>
<td>Phone: 844-345-2803</td>
<td>Fax: 844-851-0882</td>
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</table>

Overview

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

No PA | PA required
--- | ---
Copaxone® (glatiramer)§ | Aubagio® (teriflunomide)
Bafiertam® (monomethyl fumarate) | Gilenya® (fingolimod)§
Mayzent® (siponimod) | Tecfidera® (dimethyl fumarate) § m* |
Vumerity® (diroximel fumarate) | Zeposia® (ozanimod)

# This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug does not have an FDA "A"-rated generic equivalent.
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 Tecfidera® (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
5. If request is for dimethyl fumarate, a trial of Tecfidera is required or clinical rationale for prescribing the generic equivalent.

**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

**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

**Zeposia®** (ozanimod)
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 Zeposia 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. Quantity requested is ≤ 1 unit/day

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

§**Brand preferred over generic equivalent:**
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. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limit</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>
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<tr>
<td>Mayzent® (siponimod) 2mg capsule</td>
<td>30 tablets per 30 days</td>
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<tr>
<td>Mayzent® (siponimod) 0.25mg capsules</td>
<td>150 tablets per 30 days</td>
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<tr>
<td>Tecfidera® (dimethyl fumarate) §</td>
<td>60 tablets per 30 days</td>
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<tr>
<td>Vumerity (diroximel fumarate)</td>
<td>120 capsules per 30 days</td>
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<tr>
<td>Zeposia® (ozanimod) 7-day starter pack</td>
<td>1 pack</td>
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<tr>
<td>Zeposia® (ozanimod) Starter kit</td>
<td>1 pack</td>
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<tr>
<td>Zeposia® (ozanimod) 0.92mg</td>
<td>30 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

Disclaimer
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