Multiple Sclerosis Agents
Aubagio® (teriflunomide)
Bafiertam (monomethyl fumarate)
Gilenya® (fingolimod)
Mayzent® (siponimod)
Tecfidera® (dimethyl fumarate)
Vumerity® (diroxeml fumarate)
Effective 02/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	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®

No PA	PA required
Copaxone® (glatiramer)§	Aubagio® (teriflunomide)
	Bafiertam® (monomethyl fumarate)
	Gilenya® (fingolimod) §*
	Mavenclad® (cladribine tablet)
	Mayzent® (siponimod)
	Ponvory® (ponesimod)
	Tecfidera® (dimethyl fumarate) *
	Vumerity® (diroximel fumarate)

§ Brand Preferred over generic equivalents. A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

*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 the plan 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 required):
    a. For Gilenya® 0.5 mg: weight ≥40 kg
    b. For Gilenya® 0.25 mg: weight <40 kg
5. If the request is for BRAND NAME Tecfidera®, the member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to generic dimethyl fumarate (as per the Brand Name and Non-Preferred Generic Drugs Guideline)

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 fumerate AND Vumerity (diroximel fumerate)
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 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 fumerate
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:
A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

- fingolimod
- glatiramer acetate

Continuation of Therapy

- For **RRMS** and **CIS**: 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:

Copaxone (glatiramer)	12 syringes per 28 days
Aubagio® (teriflunomide)	30 capsules per 30 days
Bafiertam (monomethyl fumarate)	120 capsules per 30 days
Gilenya® (fingolimod)	30 capsules per 30 days
Mayzent® (siponimod) 2mg capsule	30 tablets per 30 days
Mayzent® (siponimod) 0.25mg capsules	150 tablets per 30 days
Ponvory® (ponesimod)	30 capsules per 30 days
Tecfidera® (dimethyl fumarate)	60 tablets per 30 days
Vumerity (diroximel fumarate)	120 capsules per 30 days

References

1. Tecfidera® [package insert]. Cambridge (MA): Biogen Idec, Inc.; 2017 Dec.
2. National Multiple Sclerosis Society [homepage on the internet]. National Multiple Sclerosis Society; 2014 [cited 2014 Aug 15]. Available at: http://www.nationalmssociety.org/.
3. Fox RJ, Miller DH, Phillips T, Hutchinson M, Havrdova E, Kita M et al. Placebo-controlled phase 3 study of oral BG-12 or glatiramer in multiple sclerosis. N Engl J Med. 2012;367:1087-97.
4. Gold R, Kappos L, Arnold DL, Bar-Or A, Giovannoni G, Selmaj K et al. Placebo-controlled phase 3 study of oral BG-12 for relapsing multiple sclerosis. N Engl J Med. 2012(a);367:1098-107.
5. Goodin DS, Frohman EM, Garmany GP. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002;58(2):169-78.
6. Bafiertam (monomethyl fumarate) [prescribing information]. High Point, NC: Banner Life Sciences LLC; April 2020.
7. Vumerity (diroximel fumarate) [prescribing information]. Cambridge, MA: Biogen Inc; January 2021.

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
03/16/2022 – Reviewed and Updated for March P&T; Guideline updated to reflect that Gilenya is no longer brand preferred. Clarified Gilenya criteria to remove question requiring step through of the generic as the agent is not yet generically available. Effective 5/1/22.
11/16/2022 – Reviewed and updated for November P&T. Gilenya becomes a brand preferred product as the generic fingolimod becomes available. Tecfidera was removed as a brand preferred product. Effective 2/1/23.

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