Multiple Sclerosis Agents
Aubagio® (teriflunomide)
GIlenya® (fingolimod)
Mayzent® (siponimod)
Tecfidera® (dimethyl fumarate)
Zeposia® (ozanimod)
Effective 01/01/2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has 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

Tecfidera (dimethyl fumarate) is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Aubagio (teriflunomide) is indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.

Gilenya (fingolimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients ≥10 years.

Mavzent (simponimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults

Zeposia (ozanimod) is indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

No PA	PA required
Copaxone® (glatiramer)§	Aubagio® (teriflunomide)
	Gilenya® (fingolimod)§
	Mayzent® (siponimod)
	Tecfidera® (dimethyl fumarate)§ PD
	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.
§ 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.**

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

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. Paid claim or physician documentation of inadequate response or adverse reaction to **TWO** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents:
   a. Aubagio® (teriflunomide)
   b. Gilenya® (fingolimod)
   c. glatiramer acetate therapy

   d. interferon therapy
   e. Ocrevus® (ocrelizumab)
   f. Tecfidera® (dimethyl fumarate)
4. Genetic testing for CYP2C9 genotype showing the member does NOT have a CYP2C9 *3/*3 genotype
5. Requested dose is appropriate based on the CYP2C9 genotype‡

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. Paid claim or physician documentation of inadequate response or adverse reaction to **TWO** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents:
   a. Aubagio® (teriflunomide)
   b. Gilenya® (fingolimod)
   c. glatiramer acetate therapy
   d. interferon therapy
   e. Ocrevus® (ocrelizumab)
   f. Tecfidera® (dimethyl 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.
- dimethyl fumarate
- fingolimod
- Glatopa
- bafiertam
- 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:

Copaxone	12 syringes per 28 days
Aubagio® (teriflunomide)	30 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
Tecfidera® (dimethyl fumarate)§ PD	60 tablets per 30 days
Zeposia® (ozanimod) 7 day starter pack	1 pack
Zeposia® (ozanimod) Starter kit	1 pack
Zeposia® (ozanimod) 0.92mg	30 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.

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

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.