Mass General Brigham
Health Plan

Multiple Sclerosis Agents:
Aubagio (teriflunomide)
Bafiertam (monomethyl fumarate)
Briumvi (ublituximab-xiiy)
Extavia (interferon β-1b)
Gilenya (fingolimod capsule)
Mavenclad (cladribine tablet)
Mayzent (siponimod)
Ocrevus (ocrelizumab)
Plegridy (peginterferon β-1a)
Ponvory (ponesimod)
Tascenso (fingolimod orally disintegrating tablet)
Tecfidera (dimethyl fumarate)
Vumerity (diroximel fumarate)
Effective 10/02/2023

Plan	☒ MassHealth UPPL ☐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			

Overview

No PA	PA required
Avonex® (interferon β-1a) Betaseron®(interferon β-1b) Copaxone®# (glatiramer) Rebif®(interferon β-1a) Tysabri®(natalizumab)	Ampyra® (dalfampridine) > 2 units/day † Aubagio® (teriflunomide) > 1 units/day † Bafiertam® (monomethyl fumarate) Briumvi (ublituximab-xiiy) DUAL Extavia®(interferon β-1b) Gilenya® (fingolimod capsule) > 1 unit/day † Mavenclad® (cladribine tablet) Mayzent® (siponimod) Ocrevus® (ocrelizumab) DUAL

No PA	PA required
	Plegridy®(peginterferon β-1a) Ponvory® (ponesimod) Tascenso®(fingolimod orally disintegrating tablet) Tecfidera® (dimethyl fumarate) > 2 units/day † Vumerity® (diroximel fumarate)

#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.
BP Brand Preferred over generic equivalents. In general, requires 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.
† A-rated generic available. Both brand and A-rated generic require PA when exceeding quantity limits, if applicable.
DUAL Agent is available through pharmacy and medical benefits.

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:

Aubagio® (teriflunomide)**, Gilenya®** (fingolimod capsule) and **Tecfidera®** (dimethyl fumarate)
ALL of the following:
1. The member has a diagnosis of ONE of the following:
    a. Clinically Isolated Syndrome (CIS)
    b. Relapse-remitting Multiple Sclerosis (RRMS)
    c. Confirmed 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 fingolimod capsule: 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 fingolimod 0.5 mg capsule: weight ≥40 kg
    b. For fingolimod® 0.25 mg capsule: 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)
ALL of the following:
1. The member has a diagnosis of ONE of the following:
    a. Clinically Isolated Syndrome (CIS)
    b. Relapse-remitting Multiple Sclerosis (RRMS)
    c. Confirmed active Secondary-Progressive MS (SPMS)*
2. Prescriber is a neurologist or consult notes from a neurology office are provided

3. Provider documents medical necessity for use of Bafiertam instead of dimethyl fumarate AND Vumerity (diroximel fumarate)
4. Quantity requested is ≤ 4 capsules/day

Briumvi® (ublituximab-xiiy)
1. Diagnosis of **ONE** of the following:
    a. clinically isolated syndrome
    b. relapse-remitting multiple sclerosis
    c. active secondary-progressive multiple sclerosis
2. Prescriber is a neurologist or consult notes from a neurology office are provided
3. Requested dose is 450 mg IV every 24 weeks (if member is initiating therapy, first dose is given as a 150 mg infusion on day 1 followed by a 450 mg infusion two weeks later)

Extavia® (interferon β-1b)
ALL of the following:
1. Diagnosis of **ONE** of the following:
    a. Clinically isolated syndrome
    b. Relapse-remitting multiple sclerosis
    c. Confirmed active secondary-progressive multiple sclerosis
2. Prescriber is a neurologist or consult notes from a neurology office are provided
3. Medical necessity for Extavia® instead of interferon β-1b (Betaseron®)

Mavenclad® (cladribine tablet)
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. teriflunomide
    b. fingolimod capsules or Mayzent (siponimod)
    c. glatiramer acetate therapy
    d. interferon therapy
    e. Briumvi (ublituximab-xiiy) or 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)
ALL of the following:
1. The member has a diagnosis of ONE of the following:
    a. Clinically Isolated Syndrome (CIS)
    b. Relapse-remitting Multiple Sclerosis (RRMS)
    c. Confirmed 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 Mayzent® instead of fingolimod capsule
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. teriflunomide
b. glatiramer acetate therapy
c. interferon therapy
d. Briumvi (ublituximab-xiiy) or Ocrevus® (ocrelizumab)
e. 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

Ocrevus® (ocrelizumab)
ALL of the following:

1. Diagnosis of **ONE** of the following:
    a. clinically isolated syndrome
    b. relapse-remitting multiple sclerosis
    c. confirmed active secondary-progressive multiple sclerosis
    d. primary progressive multiple sclerosis
2. Prescriber is a neurologist or consult notes from a neurology office are provided
3. **If reviewing under Pharmacy Benefit:** For diagnosis of CIS, RRMS, and active SPMS, inadequate response, adverse reaction, or contraindication to Briumvi® (ublituximab-xiiy)
4. Requested dose is 600 mg every 6 months (if member is initiating therapy, first 600 mg dose is given as a 300 mg infusion on day 1 followed by a second 300 mg infusion two weeks later)

Plegridy® (peginterferon β-1a)
ALL of the following:

1. Diagnosis of **ONE** of the following:
    a. clinically isolated syndrome
    b. relapse-remitting multiple sclerosis
    c. confirmed active secondary-progressive multiple sclerosis
2. Prescriber is a neurologist or consult notes from a neurology office are provided
3. Medical necessity for Plegridy® instead of interferon β-1a (Avonex®, Rebif®, Rebif Rebidose®)
4. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following non-interferon disease modifying therapies:
    a. Aubagio® (teriflunomide)
    b. fingolimod capsule
    c. glatiramer
    d. Lemtrada® (alemtuzumab)
    e. Briumvi (ublituximab-xiiy) or Ocrevus® (ocrelizumab)
    f. dimethyl fumarate or Vumerity®
    g. Tysabri® (natalizumab)
5. Requested quantity is ≤ 2 syringes or pens/28 days

Ponvory® (ponesimod)
ALL of the following:

1. The member has a diagnosis of ONE of the following:
    a. Clinically Isolated Syndrome (CIS)
    b. Relapse-remitting Multiple Sclerosis (RRMS)
    c. Confirmed active Secondary-Progressive MS (SPMS)
2. The prescriber is a neurologist or medication is being prescribed in consultation with a neurologist
3. Medical necessity for requested agent instead of fingolimod capsule

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. teriflunomide
    b. glatiramer acetate therapy
    c. interferon therapy
    d. Briumvi (ublituximab-xiiy) or Ocrevus (ocrelizumab)
    e. dimethyl fumarate or Vumerity (diroximel fumarate)
5. Quantity requested is ≤ 1 unit/day

Tascenso® ODT (fingolimod orally disintegrating tablet)
ALL of the following:
1. Diagnosis of **ONE** of the following:
    a. clinically isolated syndrome,
    b. relapse-remitting multiple sclerosis, or
    c. confirmed active secondary-progressive multiple sclerosis
2. Prescriber is a neurologist or consult notes from a neurology office are provided
3. Member is ≥ 10 years of age
4. **ONE** of the following:
    a. For 0.25 mg ODT, weight is ≤ 40 kg
    b. For 0.5 mg ODT, weight is > 40 kg
5. Medical necessity for Tascenso® ODT instead of fingolimod capsule
6. Requested quantity is ≤ 1 unit/day

Vumerity® (diroximel fumarate)
1. The member has a diagnosis of ONE of the following:
    a. Clinically Isolated Syndrome (CIS)
    b. Relapse-remitting Multiple Sclerosis (RRMS)
    c. Confirmed 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

Quantity Limit Exceeded
Ampyra® (dalfampridine)
Gilenya® (fingolimod capsule)
Tecfidera® (dimethyl fumarate)
Aubagio® (teriflunomide)
1. Medical necessity for exceeding the quantity limits

Continuation of Therapy
- For **PPMS** and **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 not be approved (max 2 years of treatment).
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
5. The following quantity limits apply:

Ampyra (dalfampridine)	60 tablets per 30 days
Aubagio® (teriflunomide)	30 capsules per 30 days
Bafiertam (monomethyl fumarate)	120 capsules per 30 days
Copaxone (glatiramer)	12 syringes per 28 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
Plegridy® (peginterferon β-1a)	2 syringes or pens per 30 days
Ponvory® (ponesimod)	30 capsules per 30 days
Tascenso® ODT (fingolimod orally disintegrating tablet)	30 tablets 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.
8. Briumvi® [package insert]. Morrisville (NC): TG Therapeutics; 2022 Dec.

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.
03/15/23 - Reviewed and updated for Mar P&T. Added criteria for Extavia, Ocrevus, Plegridy, Tascenso to policy. Changed Gilenya to fingolimod capsules throughout policy. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Updated policy to include new strength and criteria for Tascenso ODT 0.5 mg. Added weight requirement to Tascenso ODT. Effective 6/5/23
07/12/23 – Reviewed and updated for P&T. Brand preferred and mandatory generic language was added under Limitations. Added new drug, Briumvi® (ublituximab-xiiy), requiring PA through pharmacy and medical benefits. Briumvi was added as a step through option for Ocrevus for requests under PB. Dalfampridine, dimethyl fumarate, fingolimod and teriflunomide will only require PA if above QL. Effective 7/31/23
09/13/23 – Reviewed and updated for P&T. Consolidated Ocrevus and Briumvi into a single alternative option given the same mechanism of action. Effective 10/2/23