BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Medical Necessity Policy

Multiple Sclerosis – Unified Formulary

Policy Number: 9.219
Version Number: 2.2
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

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

+ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

§ Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent is required.
PD Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class is required. **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.

Approval Criteria:

Aubagio® (teriflunomide) **Gilenya®** (fingolimod) **§** **Tecfidera®** (dimethyl fumarate) **§**	1. Documented diagnosis of **ONE** of the following: a. Clinically isolate syndrome (CIS); **OR** b. Relapse-remitting multiple sclerosis (RRMS); **OR** c. Active secondary-progressive multiple sclerosis (SPMS) **AND** 2. Prescribed by a neurologist or consult notes from a neurology office are provided
Bafiertam® (monomethyl fumarate)	1. Documented diagnosis of **ONE** of the following: a. Clinically isolate syndrome (CIS); **OR** b. Relapse-remitting multiple sclerosis (RRMS); **OR** c. Active secondary-progressive multiple sclerosis (SPMS) **AND** 2. Prescribed by a neurologist or consult notes from a neurology office are provided; **AND** 3. Documented clinical rationale for medical necessity for use instead of dimethyl fumarate **AND** Vumerity (diroximel fumarate)
Mavenclad® (cladribine tablet)	1. Documented diagnosis of **ONE** of the following: a. Relapse-remitting multiple sclerosis (RRMS); **OR** b. Active secondary-progressive multiple sclerosis (SPMS) **AND** 2. Prescribed a neurologist or consult notes from a neurology office are provided; **AND** 3. Documentation member has not exceeded two years of treatment; **AND** 4. Documentation of **ONE** of the following: a. Inadequate response or adverse reaction to **THREE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents (*History of claims is sufficient for all failed trials*): i. Aubagio® (teriflunomide) ii. Gilenya® (fingolimod) or Mayzent® (siponimod) iii. glatiramer acetate therapy

	iv. interferon therapy v. Ocrevus® (ocrelizumab) vi. dimethyl fumarate or Vumerity® vii. Tysabri® (natalizumab) **OR** b. Member is new to the plan and stable on Mavenclad
Mayzent® (siponimod)	1. Documented diagnosis of **ONE** of the following: a. Clinically isolate syndrome (CIS); **OR** b. Relapse-remitting multiple sclerosis (RRMS); **OR** c. Active secondary-progressive multiple sclerosis (SPMS) **AND** 2. Prescriber is a neurologist or consult notes from a neurology office are provided; **AND** 3. Documentation of medical necessity for use instead of Gilenya®; **AND** 4. Documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents (*History of claims is sufficient for all failed trials*): a. Aubagio® (teriflunomide) b. glatiramer acetate therapy c. interferon therapy d. Ocrevus® (ocrelizumab) e. Tecfidera® (dimethyl fumarate) or Vumerity®(diroximel fumarate) **AND** 5. Documentation of genetic testing for CYP2C9 genotype showing the member does NOT have a CYP2C9 *3/*3 genotype
Vumerity® (diroximel fumarate)	1. Documented diagnosis of **ONE** of the following: a. Clinically isolate syndrome (CIS); **OR** b. Relapse-remitting multiple sclerosis (RRMS); **OR** c. Active secondary-progressive multiple sclerosis (SPMS) **AND** 2. Prescriber is a neurologist or consult notes from a neurology office are provided; **AND** 3. Documentation of medical necessity for use instead of dimethyl fumarate
Ponvory® (ponesimod)	1. Documented diagnosis of **ONE** of the following: a. Clinically isolate syndrome (CIS); **OR** b. Relapse-remitting multiple sclerosis (RRMS); **OR** c. Active secondary-progressive multiple sclerosis (SPMS) **AND** 2. Prescriber is a neurologist or consult notes from a neurology office are provided; **AND**

	3. Documentation of medical necessity for use instead of Gilenya® 4. Documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents (*History of claims is sufficient for all failed trials*): a. Aubagio® (teriflunomide) b. glatiramer acetate therapy c. interferon therapy d. Ocrevus® (ocrelizumab) e. Tecfidera® (dimethyl fumarate) or Vumerity® (diroximel fumarate)
Duration/Quantity of Authorization:	Prior authorization may be issued for **1 year**

Appendix:

Vumerity® Medical Necessity

Inadequate response to Tecfidera® (dimethyl fumarate)

- Requests documenting an IR to Tecfidera® → generally deny

Both Tecfidera® and Vumerity® are prodrugs of the same active metabolite. The efficacy of Vumerity® was based on clinical studies of Tecfidera®.

Contraindication to Tecfidera® (dimethyl fumarate)

- Requests documenting a CI to Tecfidera® → generally deny.
- If a CI is noted due to an ADR, see below.

Adverse Drug Reaction to Tecfidera® (dimethyl fumarate)

- Request documents a GI-related ADR:
  - Limited details provided → deny
  - Detailed information is provided → approve or deny based on below
- Request documents any other (non-GI related [e.g., flushing]) ADRs → generally deny

The only noted difference in ADR profile between Vumerity® and Tecfidera® are GI-related effects (e.g., diarrhea, nausea, abdominal pain). However, the clinical benefit of this difference is unclear as the GI effects of Tecfidera® are generally considered mild and typically resolve within the first two months of treatment. Furthermore, similar rates of GI effects were observed with Vumerity® in an ongoing safety study (EVOLVE-MS-1) compared to real-world data of Tecfidera® (30.9% vs 27%, respectively). Of note, taking the medication with food can decrease the rate of GI upset. The overall discontinuation rate of Tecfidera® due to side effects were low in clinical studies.

Compelling information should be documented in the medical record or letter of medical necessity. Examples include:

- Specific GI-related ADR(s) is/are documented (e.g., nausea, diarrhea)
- Severity of the ADR must be documented (e.g., stools/day, N/V, disruption in ADLs, etc.)
- Time of ADR onset relative to starting Tecfidera® should be clear and appropriate

- GI ADR has not resolved despite at least two months of treatment with Tecfidera® (can consider shorter duration if ADR is severe and mitigation strategies have been used)
- Member has used multiple mitigation strategies to alleviate GI ADRs (e.g., taking with food, use of anti-emetics or anti-diarrheals)

References

1. Aubagio (teriflunomide) [prescribing information]. Cambridge, MA: Genzyme Corporation; February 2020.
2. Bafiertam (monomethyl fumarate) [prescribing information]. High Point, NC: Banner Life Sciences LLC; April 2020.
3. Gilenya (fingolimod) [prescribing information]. Stein, Switzerland: Novartis Pharma Stein AG; December 2019.
4. Mavenclad (cladribine) [prescribing information]. Rockland, MA: EMD Serono, Inc.; 2019 March.
5. Mayzent (siponimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
6. Ponvory (ponesimod) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2021 March.
7. Tecfidera (dimethyl fumarate) [prescribing information]. Cambridge, MA: Biogen Inc.; February 2020.
8. Vumerity (diroximel fumarate) [prescribing information]. Cambridge, MA: Biogen Inc.; January 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Retired policy 9.170 Multiple Sclerosis for MH. New Policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
1/19/2021	Updated policy to reflect PUF changes as of 10/30/20	1/19/2021	P&T Committee
2/4/2021	Annual Review: Updated policy to reflect 1.22.21 State policy changes.	2/4/2021	P&T Committee

Policy Revisions History			
	Updated to add Vumerity as an acceptable trial (Vumerity or dimethyl fumarate) for Mavenclad and Zeposia, verbiage changes to quantity limit appendix, verbiage change to provider being a neurologist/consult notes for all agents.		
5/13/2021	Updated policy to reflect 2/19/21 changes from MH. Guideline updated to reflect addition of Bafiertam and Vumerity which will both require PA. Updated policy to reflect 3/18/21 change (criteria 3) for Mayzent and Zeposia. Stability section also updated to reflect change.	7/1/2021	P&T Committee
10/1/2021	Updated policy to reflect MH UPPL changes: Guideline updated to include two new agents on UPPL (Mavenclad, Ponvory). Aubagio will now be moved to the preferred column on UPPL table. Zeposia moved to its own policy to reflect UC diagnosis	1/1/2022	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when

appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.