BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Multiple Sclerosis

Policy Number: 9.212
Version Number: 2.1
Version Effective Date: 11/1/2021

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

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

Prior Authorization Policy

Products Affected:

- Aubagio (teriflunomide)
- Avonex pen (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Dalfampridine ER
- Dimethyl fumarate
- Gilenya (fingolimod)
- Glatiramer
- Kesimpta (ofatumumab)
- Mayzent (siponimod)
- Plegridy (peginterferon beta-1a)
- Rebif (interferon beta-1a)
- Tecfidera (dimethyl fumarate) (**NF)**
- Vumerity (diroximel fumarate)

The Plan may authorize coverage of the above product(s) for members meeting the following criteria:

Avonex, Betaseron, glatiramer, Plegridy, Rebif

Initial Criteria

1. Member is 18 years of age and older; AND
2. Diagnosis of relapsing multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; AND

3. Prescribed by or in consultation with a neurologist; AND
4. Will not be used in combination with another MS disease modifying agent; AND
5. Will not be given concurrently with live vaccines; AND
6. Dose does not exceed:
    a. Avonex: 30mcg per week
    b. Betaseron: 250mcg every other day
    c. Glatiramer: 20 mg daily or 40mg three times per week
    d. Plegridy: 125 mcg every two weeks
    e. Rebif:44 mcg three times per week

Approval Duration: 12 months

Reauthorization Criteria

1. Currently receiving medication via Boston Medical Center HealthNet Plan benefit or member has previously met initial approval criteria; AND
2. Prescribed by or in consultation with a neurologist; AND
3. Member is responding positively to therapy

Approval Duration: 12 months

Dalfampridine ER

Initial Criteria

1. Member is 18 years of age and older; AND
2. Diagnosis of multiple sclerosis; AND
3. Prescribing physician is a neurologist; AND
4. Prescriber attestation Timed 25-foot Walk (T25FW) completed within 8 to 45 seconds; AND
5. Documentation of past or current physical therapy; AND
6. Member is receiving concomitant treatment with a disease-modifying agent for multiple sclerosis

Approval Duration: 3 months

Reauthorization Criteria

1. Currently receiving medication via Boston Medical Center HealthNet Plan benefit or member has previously met initial approval criteria; AND
2. The prescribing physician is a neurologist; AND
3. Member has experienced a therapeutic response shown by at least one of the following:
    a. Improvement or stabilization in walking speed; OR
    b. Improvement or stabilization in an objective measure of walking ability (e.g., 6MWT, EDDS)

Approval Duration: 6 months

Aubagio, dimethyl fumarate, Tecfidera (NF), Vumerity

Initial Criteria

1. Member is 18 years of age and older; AND
2. Diagnosis of relapsing multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; AND
3. Prescribed by or in consultation with a neurologist; AND
4. Will not be used in combination with another MS disease modifying agent; AND
5. Member has tried and failed treatment with one or more of the following or the provider has indicated clinical inappropriateness with: Avonex, Betaseron, glatiramer, Plegridy, or Rebif; AND
6. For Vumerity only: member experienced intolerable GI side effects from dimethyl fumarate

7. If request is for brand Tecfidera, clinical rationale as to why generic dimethyl fumarate cannot be used.

Approval Duration: 12 months

Reauthorization Criteria

1. Currently receiving medication via Boston Medical Center HealthNet Plan benefit or member has previously met initial approval criteria; AND
2. Prescribed by or in consultation with a neurologist; AND
3. Member is responding positively to therapy **Approval Duration: 12 months**

Gilenya

Initial Criteria

1. 10 years of age or older; AND
2. Diagnosis of relapsing multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; AND
3. Prescribed by or in consultation with a neurologist; AND
4. If member is18 years of age or older, member has tried and failed treatment with one or more of the following or the provider has indicated clinical inappropriateness with: Avonex, Betaseron, glatiramer, Plegridy, or Rebif
   Approval Duration: 12 months

Reauthorization Criteria

1. Currently receiving medication via Boston Medical Center HealthNet Plan benefit or member has previously met initial approval criteria; AND
2. Prescribed by or in consultation with a neurologist; AND
3. Member is responding positively to therapy

Approval Duration: 12 months

Mayzent

Initial Criteria

1. Member is 18 years of age or older; AND
2. Diagnosis of relapsing multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; AND
3. Prescribed by or in consultation with a neurologist; AND
4. Member has tried and failed treatment with one or more of the following or the provider has indicated clinical inappropriateness with:
   a. One of the following: Avonex, Betaseron, glatiramer, Plegridy, or Rebif; AND
   b. One of the following: Vumerity, or Aubagio.

Approval Duration: 12 months

Reauthorization Criteria

1. Currently receiving medication via Boston Medical Center HealthNet Plan benefit or member has previously met initial approval criteria; AND
2. Prescribed by or in consultation with a neurologist; AND

3. Member is responding positively to therapy

Approval Duration: 12 months

Kesimpta

Initial Criteria

1. Member is 18 years of age and older; ***AND***
2. A diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; ***AND***
3. Prescribed by or in consultation with a neurologist; ***AND***
4. Requested dose does not exceed 20 mg monthly; ***AND***
5. Will not be used in combination with another MS disease modifying agent; ***AND***
6. Member has tried and failed treatment with one or more of the following or the provider has indicated clinical inappropriateness with : Avonex, Betaseron, glatiramer, Plegridy, Rebif, Aubagio, dimethyl fumarate, Gilenya, Mayzent, Zeposia, or Vumerity

Approval Duration: 12 months

Reauthorization Criteria

1. Currently receiving medication via Boston Medical Center HealthNet Plan benefit or member has previously met initial approval criteria: ; ***AND***
2. Prescribed by or in consultation with a neurologist; ***AND***
3. Member is responding positively to therapy.

Approval Duration: 12 months

Appendix A

- Disease-modifying therapies for MS are: daclizumab (Zinbryta®), glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (GilenyaTM), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocreliuzmab (OcrevusTM).

Clinical Background Information and References

1. Michale J. Olek. Comorbid problems associated with multiple sclerosis in adults. Up to Date online. Accessed June 12, 2014.
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5. Gilenya (fingolimod): prescribing information. Available at http://www.gilenya.com/index.jsp. Accessed June 12, 2014
6. Michael J Olek, DO. Treatment of relapsing-remitting multiple sclerosis in adults. Up to Date online. Last updated Apr 14, 2017. Accessed June 24, 2017

7. FDA Drug Safety Communication: Revised recommendations for cardiovascular monitoring and use of multiple sclerosis drug Gilenya (fingolimod). Available at http://www.fda.gov/Drugs/DrugSafety/ucm303192.htm. Accessed June 12, 2014.
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11. Copaxone® (glatiramer acetate): Package Insert. Available at http://www.copaxone.com. Accessed June 12, 2014
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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	9.170 Multiple Sclerosis Policy retired, new policy created.	1/1/2021	P&T Committee
2/11/2021	P&T annual review. Add dimethyl fumarate to policy and prefer it over Tecfidera and Vumerity. Add Kesimpta to policy.	6/1/2021	P&T Committee
8/12/2021	Removal of Zeposia and associated criteria from this policy and created its own drug specific policy (9.234).	11/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

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.