BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Multiple Sclerosis – Non UPPL

Policy Number: 9.212
Version Number: 2.1
Version Effective Date: 1/1/2022

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:

- dalfampridine ER
- Kesimpta
- Ocrevus

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

Covered Use	All FDA approved indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	**dalfampridine ER** 1. Indication of walking difficulty with a diagnosis of multiple sclerosis; ***AND*** 2. Prescriber attestation that there has been a deterioration of walking ability confirmed by gait assessment (e.g. MS Walking Scale 12 (MSWS-12), Timed 25-foot Walk (T25FW), 6-minute Walk Test, Expanded Disability Status Scale (EDSS) ; ***AND***

+ 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.

	3. Documentation of past or current physical therapy; ***AND*** 4. History of or current treatment with immune modulating therapies for multiple sclerosis **Kesimpta** 1. A diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; ***AND*** 2. An inadequate response, adverse, or contraindication to at least two preferred alternative medications (e.g., Tecfidera, Gilenya, Aubagio, Avonex, Betaseron, Rebif, Plegridy, Copaxone, Mayzent, Zeposia); ***AND*** 3. Requested dose does not exceed 20 mg monthly; ***AND*** 4. Provider attests that the medication will not be used in combination with another MS disease modifying agent **Ocrevus** 1. A diagnosis of primary progressive multiple sclerosis; ***OR*** 2. A diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; ***AND*** a. An inadequate response, adverse, or contraindication to at least two formulary alternative medications.
Age Restrictions	dalfampridine ER, Kesimpta: 18 years and older
Prescriber Restriction	Prescribed by or in consultation with a neurologist.
Coverage Duration	dalfampridine ER initial: 3 months dalfampridine ER reauthorization: 6 months Kesimpta, , Ocrevus: 12 months
Quantity Limit	dalfampridine ER: 2 capsules per day
Other criteria	<u>Kesimpta, Ocrevus Reauthorization:</u> Prescriber attestation that the patient's clinical condition has improved or stabilized with the current therapy with no significant adverse events. <u>dalfampridine ER Reauthorization:</u> Prescriber attestation that the patient's walking ability has improved confirmed by gait assessment.

Clinical Background Information and References

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5. Andrew D Goodman, et al. Sustained-release oral fampiridine in multiple sclerosis: a randomized, double-blind, controlled trial. Lancet 2009; 373:732-38
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17. Lemtrada (alemtuzumab): Package Insert . Available at https://www.lemtrada.com. Accessed June 24, 2015.

18. Ocrevus (ocrelizumab): Prescribing Information. Available at https://www.ocrevus.com. Accessed July 3, 2017.
19. Zinbryta (daclizumab): Prescribing Information. Available at https://www.zinbryta.com. Accessed July 3, 2017.
20. Michael J Olek. Clinical course and classification of multiple sclerosis. Up to Date online. Last update Nov 08, 2016. Accessed July 3, 2017.
21. Michael J Olek. Treatment of progressive multiple sclerosis in adults. Up to Date online. Last update Apr 17, 2017. Accessed July 3, 2017
22. Kesimpta (ofatumumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. August 2020.

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. Policy was split for MA into 9.219 MH PUF policy.	1/1/2021	P&T Committee
2/11/2021	P&T annual review. Add Kesimpta to policy. List the different types of relapsing MS for diagnoses. Add Mavenclad contraindication.	6/1/2021	P&T Committee
10/1/2021	Mavenclad moved to UPPL policy	1/1/2022	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.