BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

## Pharmacy Policy

# Multiple Sclerosis

**Policy Number:** 9.212
**Revision Number:** R0
**Version Effective Date:** 1/1/2021

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

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

## Prior Authorization Policy

**Products Affected:**

- Dalfampridine ER
- Mavenclad® (cladribine)
- Mayzent® (siponimod)
- Ocrevus® (ocrelizumab)
- Tysabri®natalizumab)

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

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| **Covered Use** | All FDA approved indications unless otherwise excluded |
| **Exclusion Criteria** | Tysabri: member currently has or has previously had progressive multifocal leukoencephalopathy (PML) |
| **Required Medical Information** | **Dalfampridine ER**<br>1. Indication of walking difficulty with a diagnosis of multiple sclerosis; ***AND***<br>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 |

+ 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.

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| | Walk Test, Expanded Disability Status Scale (EDSS) ; ***AND***<br>3. Provider attestation of past or current physical therapy; ***AND***<br>4. History of or current treatment with immune modulating therapies for multiple sclerosis<br><br>**Mavenclad, Mayzent**<br><br>1. A diagnosis of secondary progressive multiple sclerosis; ***OR***<br>2. A diagnosis of relapsing multiple sclerosis; ***AND***<br>a. A trial and failure of three of the following preferred products: Avonex, Betaseron, Copaxone, Gilenya, Glatopa, glatiramer, Tecfidera.<br><br>**Ocrevus**<br>1. A diagnosis of primary progressive multiple sclerosis; ***OR***<br>2. A diagnosis of relapsing multiple sclerosis; ***AND***<br>a. A trial and failure of three of the following preferred products: Avonex, Betaseron, Copaxone, Gilenya, Glatopa, glatiramer, Tecfidera.<br>**Tysabri**<br>1. A diagnosis of relapsing multiple sclerosis; ***AND***<br>2. Provider attestation that the member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML); ***AND***<br>3. A trial and failure of three of the following preferred products: Avonex, Betaseron, Copaxone, Gilenya, Glatopa, glatiramer, Tecfidera. |
| **Age Restrictions** | Dalfampridine ER, Tysabri: 18 years and older |
| **Prescriber Restriction** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Dalfampridine ER initial: 3 months<br>Dalfampridine ER reauthorization: 6 months<br>Mavenclad, Mayzent, Ocrevus, Tysabri: 12 months |
| **Other criteria** | Mavenclad, Mayzent, Ocrevus, Tysabri Reauthorization:<br>Prescriber attestation that the patient's clinical condition has improved or stabilized with the current therapy with no significant adverse events.<br><br>Dalfampridine ER Reauthorization:<br>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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8. 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. Michael G. Trisolini. Comparison of Multiple Sclerosis Guidelines Underscores Need for Collaboration, 2008

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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.

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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. Tysabri (natalizumab): Package Insert. Available at https://www.tysabri.com. Accessed August 28, 2020.

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
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| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee,<br>NH DHHS |

| Policy Revisions History | | | |
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| **Review Date** | **Summary of Revisions** | **Revision Effective Date** | **Approved by** |
| 12/1/2020 | 9.170 Multiple Sclerosis Policy retired, new policy created. Aligned with NH PDL | 1/1/2021 | P&T Committee, NH DHHS |

## Next Review Date

2021

## 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.