Mass General Brigham
Health Plan

Mavenclad (cladribine) Effective 11/01/2025			
Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Mavenclad (cladribine) is a purine antimetabolite indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS.

Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The recommended cumulative dosage of Mavenclad is 3.5 mg/kg administered orally and divided into 2 yearly treatment courses (1.75 mg/kg per treatment course). Each treatment course is divided into 2 treatment cycles:

- Administration of First Treatment Course:
  - First Course/First Cycle: start any time
  - First Course/Second Cycle: administer 23 to 27 days after the last dose of the First Course/First Cycle
- Administration of Second Treatment Course:
  - Second Course/First Cycle: administer at least 43 weeks after the last dose of First Course/Second Cycle
  - Second Course/Second Cycle: administer 23 to 27 days after the last dose of Second Course/First Cycle

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days 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 will be granted when all of the following criteria are met:

1. Member has one of the following diagnoses:
   a. Relapsing-remitting multiple sclerosis (RRMS)
   b. Active secondary progressive multiple sclerosis (SPMS)
2. Member is 18 years of age or older

3. Requested medication is prescribed by or in consultation with a neurologist
4. Member meets ONE of the following:
    a. Member has had an inadequate response or adverse reaction to THREE of the following disease modifying MS agents:
        i. Teriflunomide
        ii. Fingolimod or Mayzent
        iii. Glatiramer
        iv. Interferon
        v. Ocrevus or Ocrevus Zunovo
        vi. Dimethyl fumarate
        vii. Tysabri
        viii. Lemtrada
        ix. Kesimpta
        x. Vumerity
    b. Member has a contradiction to <u>all</u> disease modifying MS agents

Limitations

1. Approvals will be granted for one 12-month cycle with one allowable refill for the second- year cycle.

References

1. Brown JWL, Coles A, Horakova D, et al. Association of Initial Disease-Modifying Therapy With Later Conversion to Secondary Progressive Multiple Sclerosis. JAMA 2019; 321:175
2. Brownlee WJ, Hardy TA, Fazekas F, Miller DH. Diagnosis of multiple sclerosis: progress and challenges. Lancet 2017; 389:1336
3. Comi G, Cook S, Rammohan K et al. Long-term effects of cladribine tablets on MRI activity outcomes in patients with relapsing-remitting multiple sclerosis: the Clarity extension study. Ther Adv Neurol Disord. 2018; 11:1-11
4. Koch M, Kingwell E, Rieckmann P, et al. The natural history of secondary progressive multiple sclerosis. J Neurol Neurosurg Psychiatry 2010; 81:1039
5. Mavenclad (cladribine) [prescribing information]. Rockland, MA: EMD Serono Inc; May 2024.
6. Montalban X, Gold R, Thompson AJ, et al. ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis [published correction appears in *Eur J Neurol*. 2018;25(3):605]. *Eur J Neurol*. 2018;25(2):215-237. doi: 10.1111/ene.13536.
7. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in *Neurology*. 2019;92(2):112]. *Neurology*. 2018;90(17):777-788. doi: 10.1212/WNL.0000000000005347
8. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol 2018; 17:162
9. University of California, San Francisco MS-EPIC Team, Cree BAC, Hollenbach JA, et al. Silent progression in disease activity-free relapsing multiple sclerosis. Ann Neurol 2019; 85:653

<u>Review History</u>

09/18/19 – Reviewed
09/16/20 – Reviewed at P&T
09/22/2021 – Reviewed at P&T; no clinical updates.

07/11/2025 – Reviewed and updated at July P&T. Updated language for members who are new to the Plan. Added Lemtrada, Kesimpta, Vumerity and Ocrevus Zunovo to the list of previous trial options. Effective 11/01/2025.