Mass General Brigham
Health Plan

Mavenclad (cladribine)
Effective 12/1/2019

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Cladribine is a nucleoside inhibitor. Currently the intravenous formulation is available as an antineoplastic agent. Mavenclad is the oral formulation of cladribine FDA approved for the treatment in adults with relapsing-remitting multiple sclerosis (RRMS) and active secondary progressive multiple sclerosis (SPMS). The proposed mechanism of action in MS involves cytotoxic effects on B and T lymphocytes which results in the depletion of lymphocytes.

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Mavenclad excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

Approval of Mavenclad will be granted if the member meets all following criteria and documentation has been submitted:

1. The member is at least 18 years of age **AND**
2. The member has diagnosis of RRMS† or active SPMS‡
3. The prescriber is a neurologist or neurology consult notes are provided
4. The member has had an inadequate response or adverse reaction to THREE of the following disease modifying MS agents:
    a. Aubagio
    b. Gilenya or Mayzent
    c. Glatiramer therapy
    d. Interferon therapy
    e. Ocrevus
    f. Tecfidera

g. Tysabri

OR

5. The member has a contradiction to all disease modifying MS agents

†RRMS is characterized by clearly defined attacks (relapses or exacerbations) with full or incomplete recovery. There is minimal disease progression during the periods between relapses.
‡ SPMS is characterized by an initial relapsing-remitting MS disease course followed by gradual worsening with or without occasional relapses, minor relapses, and plateaus. Active SPMS is defined as having at least one relapse in the past two years. There are no established criteria to determine when RRMS coverts to SPMS.

Limitations

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

References

1. Mavenclad (cladribine) [prescribing information]. Rockland, MA: EMD Serono Inc; April 2019
2. 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
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. 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.
5. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol 2018; 17:162
6. 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
7. Koch M, Kingwell E, Rieckmann P, et al. The natural history of secondary progressive multiple sclerosis. J Neurol Neurosurg Psychiatry 2010; 81:1039
8. Brownlee WJ, Hardy TA, Fazekas F, Miller DH. Diagnosis of multiple sclerosis: progress and challenges. Lancet 2017; 389:1336
9. Aubagio (teriflunomide) [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2019
10. 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
11. Gilenya (fingolimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019
12. Copaxone (glatiramer acetate) [prescribing information]. North Wales, PA: Teva Pharmaceuticals; March 2020
13. Rebif (interferon beta-1a) [prescribing information]. Rockland, MA: EMD Serono Inc; May 2020.
14. Mayzent (siponimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019
15. Ocrevus (ocrelizumab) [prescribing information]. South San Francisco, CA: Genetech Inc; May 2020
16. Tecfidera (dimethyl fumarate) [prescribing information]. Cambridge, MA: Biogen Idec Inc; February 2020
17. Tysabri (natalizumab) [prescribing information]. Cambridge, MA: Biogen Inc; June 2020

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