Pharmacy Medical Necessity Guidelines: Mavenclad® (cladribine) tablets

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

Mavenclad (cladribine) is available as an oral tablet.

Note: The Mavenclad (cladribine) tablets Medical Necessity Guideline does not apply to generic cladribine intravenous solution that is FDA-approved for Hairy cell leukemia.

COVERAGE GUIDELINES

The plan may authorize coverage of Mavenclad (cladribine) for Members, when all of the following criteria are met:

1. Documented diagnosis of relapsing multiple sclerosis

AND

2. Prescribed by or in consultation with a neurologist

AND

3. The Member is at least 18 years of age

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to **two (2)** or contraindication to all of the following:
        i. Aubagio
        ii. Gilenya
        iii. glatiramer acetate therapy
        iv. interferon therapy
        v. Ocrevus
        vi. Tecfidera
    b. Member is new to the plan and stable on Mavenclad

LIMITATIONS

- Mavenlcad has a quantity limitation of 10 tablets per month.

CODES

None

REFERENCES

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2. Harrison DM. In the clinic. Multiple sclerosis. *Ann Intern Med*. 2014; 160(7):ITC4-2-ITC4-18.
3. Lublin FD, Reingold SC, Cohen JA et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014; 83: 278-86.
4. Mavenclad (cladribine) [prescribing information]. Rockland, MA: EMD Serono, Inc.; 2019 March.
5. National Institute for Health and Care Excellence (NICE). Ocrelizumab for treating primary progressive multiple sclerosis [ID938]. 2017a January. URL: nice.org.uk/guidance/indevelopment/gid-ta10153. Available from Internet. Accessed 2017 March 16.
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8. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018 April;90(17):777-88.
9. Ryan M, Deno S, Zwibel HL. Review of the clinical debate regarding interventions for multiple sclerosis. *JMCP*. 2009; 15(1):S2-17.
10. Scolding N, Barnes D, Cader S et al. Association of British neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. *Pract Neurol.* 2015; 15(4):273-9.
11. Wingerchuk DM, Weinshenker BG. Disease modifying therapies for relapsing multiple sclerosis. *BMJ.* 2016; 354: i3518.

APPROVAL HISTORY

September 10, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. March 6, 2020: Changed the name of the Medical Necessity Guideline to "Mavenclad (cladribine) tablets". Added the following Note, "The Mavenclad (cladribine) Medical Necessity Guideline does not apply to generic cladribine intravenous solution that is FDA-approved for Hairy cell leukemia."
2. November 24, 2020: Effective January 1, 2021, Tufts Health Together and Tufts Health RITogether removed from the Medical Necessity Guideline; coverage of Mavenclad in Multiple Sclerosis Agents Medical Necessity Guidelines (ID: 6036676, 2295438). Removed reauthorization criteria. Updated prerequisite criteria to an inadequate response or adverse reaction to two or contraindication to all of the following: Aubagio, Gilenya, glatiramer acetate therapy, interferon therapy, Ocrevus, or Tecfidera and the stability language to "Member is new to the plan and stable on Mavencald." Removed the Limitation "The plan will not authorize Mavenclad (cladribine) for the treatment of clinically isolated syndrome."

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.