Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Mavenclad® (cladribine) Tablets**

Effective: March 10, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) – 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 (CI S) 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Mavenclad for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of relapsing multiple sclerosis

AND

2. Documentation of **one (1)** of the following:
    a. Trial and failure with one (1) of the following alternate disease-modifying multiple sclerosis agents: Aubagio, Plegridy, interferon beta-1a, interferon beta-1b, glatiramer acetate, an oral fumarate product, a sphingosine 1-phosphate receptor modulator product, a B-cell targeted product, Tysabri, or Lemtrada
    b. Contraindication to ALL of the following disease-modifying multiple sclerosis agents: Interferon therapy, glatiramer acetate therapy, oral fumarates, sphingosine 1-phosphate receptor modulators, B-cell targeted therapies, and Aubagio
    c. The patient is already being treated with Mavenclad

Limitations

1. Samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and will not be considered for prior authorization.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Mavenclad (cladribine) [prescribing information]. Rockland, MA: EMD Serono Inc; September 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- July 11, 2023: No changes
- June 11, 2024: No changes (eff 6/11/24)
- April 8, 2025: No changes (eff 4/8/25)

- March 10, 2026: Administrative update to the limitation statement to include members initiated on the requested medication by self-paying for the medication directly do not qualify for established clinical response. Administrative update to remove CareLink from Medical Necessity Guideline template

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.