UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3123-6
Program	Step Therapy
Medication	Mavenclad® (cladribine)
P&T Approval Date	11/2019, 1/2021, 1/2022, 1/2023, 1/2024, 1/2025
Effective Date	4/1/2025

1. Background:

Step therapy programs are utilized to encourage use of lower cost, preferred alternatives for certain therapeutic classes. This program requires a member to try one disease modifying therapy before providing coverage for Mavenclad® (cladribine).

Mavenclad 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, the 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.[1]

According to the American Academy of Neurology, the benefit of initiating disease modifying therapy (DMT) has not been studied in currently untreated people with clinically isolated syndromes (CIS). It is unknown what the risk of harm is from initiating DMTs, including adverse events and burden of taking a long-term medication, relative to the benefit of reducing relapse rate.[2]

Mavenclad is not recommended for use in patients with CIS because of its safety profile.[1]

The recommended cumulative dosage of Mavenclad is divided into 2 yearly treatment courses. Each treatment course is divided into 2 treatment cycles with the 2nd cycle administered 23-27 days after the last dose of the 1st cycle. Additional cycles of Mavenclad are not to be administered after the completion of the 2nd treatment course. The safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied.

Members currently on Mavenclad as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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2. Coverage Criteria[a]:

A. Relapsing Forms of Multiple Sclerosis (MS)

1. **Mavenclad** will be approved based on **both** of the following criteria:

   a. **One** of the following:

      i. Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to **one** of the following disease-modifying therapies for MS [document medication used, dose, and duration]:

- Interferon β-1a (e.g., Avonex®, Rebif®, Plegridy®)
- Interferon β-1b (e.g., Betaseron®)
- Glatiramer acetate (e.g., Copaxone®)
- Dimethyl fumarate (e.g., Tecfidera®)
- Teriflunomide (e.g. Aubagio®)
- Fingolimod (e.g., Gilenya®)
- Mayzent® (siponimod)
- Tysabri® (natalizumab)
- Ocrevus® (ocrelizumab)
- Lemtrada® (alemtuzumab)
- Zeposia® (ozanimod)
- Kesimpta® (ofatumumab)
- Bafiertam®(monomethyl fumarate)
- Briumvi (ublituximab)

-OR-

      ii. **Both** of the following:

         (a) Patient is currently on Mavenclad

-AND-

         (b) Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from an EMD Serono sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Mavenclad*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from an EMD Serono sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

-AND-

   b. Patient has not exceeded the FDA-recommended limit of 2 treatment courses (4

treatment cycles) of Mavenclad

Authorization will be issued for 2 months. (Duration of coverage will be limited to 2 authorizations to allow 2 cumulative treatment courses [4 treatment cycles] of Mavenclad therapy.)

B. Other Diagnoses

1. Mavenclad will be approved

Authorization will be issued for 2 months. (Duration of coverage will be limited to 2 authorizations to allow 2 cumulative treatment courses [4 treatment cycles] of Mavenclad therapy.)

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Mavenclad [package insert]. EMD Serono, Inc. Rockland, MA. May 2024.
2. 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. Neurology. 2019;92(2):112-112.

Program	Prior Authorization/Step Therapy – Mavenclad® (cladribine)
Change Control	
11/2019	New program.
1/2021	Updated program requiring trial of one disease-modifying therapy. Updated authorization duration.
1/2022	Annual review with no changes to criteria.
1/2023	Annual review with no change to coverage criteria. Updated fingolimod with Gilenya as an example. Updated reference.
1/2024	Annual review with no change to coverage criteria. Updated teriflunomide with Aubagio as an example.
1/2025	Annual review. Added Briumvi as a try/fail option. Updated reference.