UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1349-6
Program	Prior Authorization/Notification
Medication	Mavenclad® (cladribine)
P&T Approval Date	1/2021, 1/2022, 1/2023, 1/2024, 1/2025, 4/2025
Effective Date	7/1/2025

1. Background:

Mavenclad® (cladribine) is 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. Mavenclad is not recommended for use in patients with clinically isolated syndrome (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.

2. Coverage Criteria[a]:

A. Relapsing Forms of Multiple Sclerosis

1. **Initial Authorization**

a. **Mavenclad** will be approved based on the following criterion:

(1) Diagnosis of relapsing forms of multiple sclerosis (MS)

-AND-

(2) Patient has not already received the FDA-recommended limit of 2 lifetime treatment courses (4 treatment cycles) of Mavenclad

Authorization will be issued for 2 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Mavenclad

-AND-

(2) Patient has not already received the FDA-recommended limit of 2 lifetime treatment courses (4 treatment cycles) of Mavenclad

Authorization will be issued for 2 months. (Duration of coverage will be limited to 1 reauthorization 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 and/or Step Therapy may be in place.

4. References:

1. Mavenclad [package insert]. Rockland, MA: EMD Serono, Inc.; May 2024.

Program	Prior Authorization/Notification – Mavenclad (cladribine)
Change Control	
1/2021	New program.
1/2022	Annual review with no change to clinical criteria.
1/2023	Annual review. Added state mandate footnote. Updated reference.
1/2024	Annual review with no change to clinical criteria.
1/2025	Annual review with no change to clinical criteria. Updated reference.
4/2025	Added statement to initial criteria "Patient has not already received the FDA-recommended limit of 2 lifetime treatment courses (4 treatment cycles) of Mavenclad" and revised similar statement in reauthorization criteria to clarify maximum recommended lifetime treatment.