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 two disease modifying therapies 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

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.

2. **Coverage Criteria:****

**A. Relapsing Forms of Multiple Sclerosis (MS)**

1. **Mavenclad** will be approved based on one of the following criteria:
   
a. Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to two of the following disease-modifying therapies for MS [document medication used, dose, and duration]:

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- Interferon β-1a (Avonex®, Rebif®, Plegridy™)
- Interferon β-1b (e.g., Betaseron®)
- Glatiramer acetate (e.g., Copaxone®)
- Tecfidera® (dimethyl fumarate)
- Aubagio® (teriflunomide)
- Gilenya® (fingolimod)
- Mayzent® (siponimod)
- Tysabri® (natalizumab)
- Ocrevus® (ocrelizumab)
- Lemtrada® (alemtuzumab)

-OR-

b. **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.

**Authorization will be issued for 12 months.**

B. **Other Diagnoses**

1. Mavenclad will be approved

**Authorization will be issued for 12 months.**

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:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Step Therapy – Mavenclad® (cladribine)</th>
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<tbody>
<tr>
<td>11/2019</td>
<td>New program.</td>
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