I. Medication Description

Cladribine is a purine antimetabolite indicated for the treatment of relapsing forms of multiple sclerosis (MS), including relapsing-remitting disease and active secondary progressive disease, in adults. The mechanism by which cladribine exerts its therapeutic effects in patients with multiple sclerosis has not been fully elucidated but is thought to involve cytotoxic effects on B and T lymphocytes through impairment of DNA synthesis, resulting in a dose-dependent reduction in lymphocyte count.

Because of its safety profile, 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.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Mavenclad is available when the following criteria have been met:

- Member has a diagnosis of a relapsing form of multiple sclerosis (MS) including relapsing-remitting MS (RRMS) or active secondary progressive disease (SPMS) AND
- Member does NOT have a diagnosis of clinically isolated syndrome (CIS) AND
- Medication is prescribed by or in consultation with a neurologist AND
- Member is 18 years of age or older AND
- Member has had an inadequate response to, or is unable to tolerate, at least ONE alternate drug indicated for the treatment of a relapsing form of MS AND
- Member’s current weight is submitted AND
- A baseline (within 3 months) MRI scan is obtained prior to starting the first treatment course because of the risk of progressive multifocal leukoencephalopathy (PML)

IV. Quantity Limitations

Coverage is available for 1.75mg/kg per treatment course, divided into 2 treatment cycles. Coverage will be provided up to maximum of 10 tablets per 27 days (one cycle), according to the table below.
Dose of Mavenclad per cycle by patient weight in each treatment course:

<table>
<thead>
<tr>
<th>Weight Range (kg)</th>
<th>Dose in mg (Number of 10 mg Tablets) per Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First Cycle</td>
</tr>
<tr>
<td>40 to less than 50</td>
<td>40 mg (4 tablets)</td>
</tr>
<tr>
<td>50 to less than 60</td>
<td>50 mg (5 tablets)</td>
</tr>
<tr>
<td>60 to less than 70</td>
<td>60 mg (6 tablets)</td>
</tr>
<tr>
<td>70 to less than 80</td>
<td>70 mg (7 tablets)</td>
</tr>
<tr>
<td>80 to less than 90</td>
<td>80 mg (8 tablets)</td>
</tr>
<tr>
<td>90 to less than 100</td>
<td>90 mg (9 tablets)</td>
</tr>
<tr>
<td>100 to less than 110</td>
<td>100 mg (10 tablets)</td>
</tr>
<tr>
<td>110 and above</td>
<td>100 mg (10 tablets)</td>
</tr>
</tbody>
</table>

V. Coverage Duration

Coverage is provided for 2 months to accommodate one treatment course (two treatment cycles) and can be renewed once per lifetime.

Administration of First Treatment Course
- First Course/First Cycle: start any time.
- First Course/Second Cycle: administer 23 to 27 days after the last dose of First Course/First Cycle.

Administration of Second Treatment Course
- Second Course/First Cycle: administer at least 43 weeks after the last dose of First Course/Second Cycle.
- Second Course/Second Cycle: administer 23 to 27 days after the last dose of Second Course/First Cycle.

VI. Coverage Renewal Criteria

Coverage for the second treatment course may be provided based upon the following criteria:
- At least 43 weeks have elapsed since the last dose of the First course/second cycle AND
- Member has not yet received a lifetime maximum of 2 courses (4 cycles) of therapy with Mavenclad AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- Mavenclad is available as 10mg tablets.
VIII. Summary of Policy Changes

- 7/15/19: new policy
- 11/15/19: no policy changes

IX. References

2. UpToDate, accessed August 2019
3. Facts and Comparisons Online, accessed May 2019

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*