# Mavenclad (cladribine)
Effective 12/1/2019

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<tr>
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<th>☒ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
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<th>☐ Step Therapy</th>
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<tbody>
<tr>
<td>Benefit</td>
<td>☒ Pharmacy Benefit</td>
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<tr>
<td>Specialty Limitations</td>
<td>This medication has been designated specialty and must be filled at a contracted specialty pharmacy.</td>
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## Specialty Medications
- **All Plans**: Phone: 866-814-5506, Fax: 866-249-6155

## Non-Specialty Medications
- **MassHealth**: Phone: 877-433-7643, Fax: 866-255-7569
- **Commercial**: Phone: 800-294-5979, Fax: 888-836-0730
- **Exchange**: Phone: 855-582-2022, Fax: 855-245-2134

## Medical Specialty Medications (NLX)
- **All Plans**: Phone: 844-345-2803, Fax: 844-851-0882

## Exceptions
- N/A

### Overview
Cladribine is a nucleoside inhibitor. Currently the intravenous formulation is available as an antineoplastic agent. Mavenclad is the oral formulation of cladribine FDA approved for the treatment in adults with relapsing-remitting multiple sclerosis (RRMS) and active secondary progressive multiple sclerosis (SPMS). The proposed mechanism of action in MS involves cytotoxic effects on B and T lymphocytes which results in the depletion of lymphocytes.

### Coverage Guidelines
Authorization may be granted for members who are currently receiving treatment with Mavenclad excluding when the product is obtained as samples or via manufacturer’s patient assistance program **OR**

Approval of Mavenclad will be granted if the member meets all following criteria and documentation has been submitted:

1. The member is at least 18 years of age **AND**
2. The member has diagnosis of RRMS† or active SPMS‡
3. The prescriber is a neurologist or neurology consult notes are provided
4. The member has had an inadequate response or adverse reaction to THREE of the following disease modifying MS agents:
   a. Aubagio
   b. Gilenya or Mayzent
   c. Glatiramer therapy
   d. Interferon therapy
   e. Ocrevus
   f. Tecfidera
   g. Tysabri
OR

5. The member has a contradiction to all disease modifying MS agents

†RRMS is characterized by clearly defined attacks (relapses or exacerbations) with full or incomplete recovery. There is minimal disease progression during the periods between relapses.
‡ SPMS is characterized by an initial relapsing-remitting MS disease course followed by gradual worsening with or without occasional relapses, minor relapses, and plateaus. Active SPMS is defined as having at least one relapse in the past two years. There are no established criteria to determine when RRMS converts to SPMS.

Limitations

1. Approvals will be granted for one 12-month cycle with one allowable refill for the second-year cycle.

References

8. Aubagio (teriflunomide) [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2019
10. Gilenya (fingolimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019
11. Copaxone (glatiramer acetate) [prescribing information]. North Wales, PA: Teva Pharmaceuticals; March 2020
13. Mayzent (siponimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019
15. Ocrevus (ocrelizumab) [prescribing information]. South San Francisco, CA: Genetech Inc; May 2020
16. Tecfidera (dimethyl fumarate) [prescribing information]. Cambridge, MA: Biogen Idec Inc; February 2020
17. Tysabri (natalizumab) [prescribing information]. Cambridge, MA: Biogen Inc; June 2020

Review History
09/18/19 – Reviewed
09/16/20 – Reviewed at P&T

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