# Mavenclad (cladribine)
## Effective 12/1/2019

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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 an oral formulation 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
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 coverts to SPMS.

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

**References**
1. Mavenclad (cladribine) [prescribing information]. Rockland, MA: EMD Serono Inc; April 2019
9. Aubagio (teriflunomide) [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2019
10. Gilenya (fingolimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019
11. Copaxone (glatiramer acetate) [prescribing information]. North Wales, PA: Teva Pharmaceuticals; September 2018
12. Rebif (interferon beta-1a) [product monograph]. Mississauga, Ontario, Canada: EMD Serono; August 2016
13. Mayzent (siponimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019
14. Ocrevus (ocrelizumab) [prescribing information]. South San Francisco, CA: Genetech Inc; July 2019
15. Tecfidera (dimethyl fumarate) [prescribing information]. Cambridge, MA: Biogen Idec Inc; July 2019
16. Tysabri (natalizumab) [prescribing information]. Cambridge, MA: Biogen Inc; April 2018

Review History
09/18/19 – Reviewed

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