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Cladribine Prior Authorization

Drug(s) Applied:	Cladribine

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Relapsing Multiple Sclerosis** as indicated by chart notes within the past 120 days
  1. Diagnosis of relapsing multiple sclerosis (relapsing-remitting (RRMS) or secondary progressive (SPMS)) **and**
  2. If for SPMS, patient is ambulatory **and**
  3. Patient has highly active MS disease activity & both of the following:
     a) Patient has greater than or equal to 2 relapses in the previous year **and**
     b) Patient has greater than or equal to 1 gadolinium enhancing lesion on MRI or significant increase in T2 lesion load compared with a previous MRI **and**
  4. Patient has failed an adequate trial of at least 2 (two) unique classes of disease-modifying therapy (i.e., monoclonal antibodies- ocrelizumab, rituximab, natalizumab; fingolimod; teriflunomide; dimethyl fumarate; glatiramer/Glatopa; interferons- Betaseron, Plegridy) **and**
  5. A complete differential CBC has been performed, with results demonstrating lymphocyte count is within normal limits **and**
  6. Chart notes do not indicate that the patient has **any** of the following:
     a) Active malignancy
     b) Active chronic infections (e.g., hepatitis or tuberculosis)
     c) HIV infection
     d) Pregnancy status
     e) Breastfeeding while receiving cladribine treatment and for 10 days after the last dose **and**
  7. Prescribed by or in consultation with a neurologist
  8. Patient has not exceeded 2 treatment courses or 4 cycles (2 cycles per year within the past 2 years) of treatment with cladribine (Mavenclad)

Approval Duration: 8 weeks

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II. Continued Therapy Criteria

A. Relapsing Multiple Sclerosis as indicated by chart notes within past 12 months

1. Chart notes indicate patient has been on requested drug as a continuation of therapy and has documented clinical benefit (e.g., stabilization or improvement in relapses and/or symptoms) with the requested drug **and**
2. If for SPMS, patient is ambulatory **and**
3. A differential CBC has been performed, with results demonstrating a lymphocyte count of at least 800 cells/microliter **and**
4. Chart notes do not indicate that the patient has **any** of the following:
    a) Active malignancy
    b) Active chronic infections (e.g., hepatitis or tuberculosis)
    c) HIV infection
    d) Pregnancy status
    e) Breastfeeding while receiving cladribine treatment and for 10 days after the last dose **and**
5. Prescribed by or in consultation with a neurologist **and**
6. Patient has not exceeded 4 treatment cycles or 2 treatment courses (i.e., no more than 2 cycles per year over the past 2 years) and **one** of the following applies:
    a) If the request is for the second cycle of the same treatment course, at least 23-27 days have passed since the last dose of the first cycle, **or**
    b) If the request is for the first cycle of a new (second) treatment course, at least 43 weeks have passed since the last dose of the second cycle from the previous treatment course

Approval Duration: 4 weeks if request is per cycle, 8 weeks if request is per course
Lifetime limit: 2 courses (4 cycles)

References:

1. Mavenclad prescribing information. EMD Serono, Inc. May 2026.
2. Multiple Sclerosis Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principals and Current Evidence. Updated June 2019. National Multiple Sclerosis Society. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf.
3. Institute for Clinical and Economic Review (ICER). Oral and Monoclonal Antibody Treatments for Relapsing Forms of Multiple Sclerosis: Effectiveness and Value. February 21, 2023.
4. Rae-Grant, Alexander, MD, et al. Practice Guideline Recommendations Summary: Disease-Modifying Therapies for Adults with Multiple Sclerosis. Neurology. 2018;90:777-788. Reaffirmed October 2024.

5. Corboy, John R, MD, et al. Comment on 2018 American Academy of Neurology Guidelines on Disease-Modifying Therapies in MS. Neurology. 2018;90:1106-1112.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol 2018; 17:162-73.
7. National Multiple Sclerosis Society 2017 McDonald MS Diagnostic Criteria. Available at: https://www.nationalmssociety.org/For-Professionals/Clinical-Care/Diagnosing-MS/Diagnosing-Criteria.

Policy Owned by: Curative PBM team