CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Mavenclad (cladribine)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

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, 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. It is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile, and has a black box warning for malignancy and risk of teratogenicity.
The recommended cumulative dosage is divided into 2 yearly treatment courses, with each course divided into 2 cycles. Safety and efficacy of additional treatment beyond completion of this 2-year regimen has not been studied and will not be authorized.

Mavenclad (cladribine) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 18 years of age (and weighs at least 40 kg); AND
2. Medication must be prescribed by, or in consultation with, a neurologist; AND
3. Chart notes have been provided confirming diagnosis of one of the following:
   a) Relapsing-remitting MS with at least 1 relapse in the past year
   b) Secondary progressive MS; AND
4. Chart notes must show all of the following assessments have been or will be completed:
   a) Complete blood count including lymphocyte count
   b) Liver function tests
   c) Screening for tuberculosis and hepatitis (B and C); AND
5. Member does NOT have any of the following:
   a) Current malignancy
   b) HIV infection
   c) Active chronic infections (e.g., hepatitis or tuberculosis)
   d) Clinically Isolated Syndrome (CIS)
   e) Pregnancy or breastfeeding
   f) Refusal to use effective contraception (all men and women of reproductive potential); AND
6. Member meets one of the following:
a) Documented trial and failure or contraindication to at least two other multiple sclerosis drugs, one of which must be Lemtrada, Tysabri, or Ocrevus
b) Highly active disease (aggressive or rapidly evolving) in the expert opinion of the prescriber.
7. **Dosage allowed/Quantity limit:**

Cumulative dosage of 3.5 mg/kg orally and divided into 2 yearly treatment courses (1.75 mg/kg per treatment course). Each treatment course is divided into 2 treatment cycles. Drug dose in mg and number of tablets per cycle depend on member's weight; see prescribing information for details.
First Treatment Course: First Cycle: start any time. Second Cycle: administer 23 to 27 days after the last dose of first cycle.
Second Treatment Course: First Cycle: administer at least 43 weeks after the last dose of First Course/Second Cycle. Second Cycle: administer 23 to 27 days after the last dose first cycle

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes must document positive clinical response compared to baseline such as fewer relapses or slowed progression of disability; AND
2. At least 43 weeks have elapsed since completing the second cycle of the first treatment course.

If all the above requirements are met, the medication will be approved for an additional 3 months.
*****MAX 2 TREATMENT COURSES PER LIFETIME*****

CareSource considers Mavenclad (cladribine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/02/2019	New policy for Mavenclad created.
07/13/2022	Transferred to new template. Updated all references. Moved reproductive warning to list with other contraindications. Moved TB test into list of other baseline assessments. Added at least 1 relapse in past yr to RRMS. Changed total number of failed therapies to 2 instead of 3 and added highly active disease option. Shortened initial approval duration to 3 mo and added renewal criteria allowing them to complete both courses.

References:

1. Mavenclad [prescribing information]. EMD Serono, Inc.; 2019.
2. Siddiqui MK, Khurana IS, Budhia S, Hettle R, Harty G, Wong SL. Systematic literature review and network meta-analysis of cladribine tablets versus alternative disease-modifying treatments for relapsing-remitting multiple sclerosis. *Curr Med Res Opin*. 2018;34(8):1361-1371. doi:10.1080/03007995.2017.1407303
3. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2
4. Montalban X, Gold R, Thompson AJ, et al. ECTRIMS/EAN Guideline on the pharmacological treatment of people with multiple sclerosis [published correction appears in Mult Scler. 2020 Apr;26(4):517]. *Mult Scler*. 2018;24(2):96-120. doi:10.1177/1352458517751049
5. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed July 13, 2022.
6. Giovannoni G, Comi G, Cook S, et al. A placebo-controlled trial of oral cladribine for relapsing multiple sclerosis. *N Engl J Med*. 2010;362(5):416-426. doi:10.1056/NEJMoa0902533
7. Giovannoni G, Comi G, Rammohan K, et al. Long-Term Disease Stability Assessed by the Expanded Disability Status Scale in Patients Treated with Cladribine Tablets 3.5 mg/kg for Relapsing Multiple Sclerosis: An Exploratory Post Hoc Analysis of the CLARITY and CLARITY Extension Studies. *Adv Ther*. 2021;38(9):4975-4985. doi:10.1007/s12325-021-01865-w
8. Giovannoni G, Mathews J. Cladribine Tablets for Relapsing-Remitting Multiple Sclerosis: A Clinician's Review. *Neurol Ther*. 2022;11(2):571-595. doi:10.1007/s40120-022-00339-7

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