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:

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3. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. . 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]. . 2018;24(2):96-120. doi:10.1177/1352458517751049
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6. Giovannoni G, Comi G, Cook S, et al. A placebo-controlled trial of oral cladribine for relapsing multiple sclerosis. . 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. . 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. . 2022;11(2):571-595. doi:10.1007/s40120-022-00339-7

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