Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Mavenclad (cladribine)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— based on weight
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Mavenclad (cladribine) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS, ACTIVE SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis; AND
4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Chart notes submitted with baseline of ALL of the following:
   a) Complete blood count;
   b) Lymphocyte count;
   c) Liver function test; AND
6. Member does **not** have any of the following:
   a) Current malignancy;
   b) HIV infection;
   c) Active chronic infections (e.g., hepatitis or tuberculosis); AND
7. One of the following:
   a) If female, she must:
      i) be post-menopausal or surgically sterilized; OR
      ii) uses a hormonal contraceptive, intra uterine device, diaphragm with spermicide, or condom with spermicide, for the duration of the treatment; AND
      iii) be neither pregnant nor breast-feeding;
   b) If male, he must be willing to use contraception to avoid pregnancies; AND
8. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug) and one of the following infusions: Lemtrada, Tysabri or Ocrevus.
9. **Dosage allowed:** Cumulative dosage of 3.5 mg/kg administered orally and divided into 2 treatment courses (1.75 mg/kg per treatment course). Each treatment course is divided into 2 treatment cycles.

Drug dose in mg and amount of tablets per cycle depend on member's weight, please see prescribing information for details.
Administration of First Treatment Course:
First Cycle: start any time.
Second Cycle: administer 23 to 27 days after the last dose of First Course/First Cycle.
Administration of 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 of Second Course/First Cycle.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Medication will not be reauthorized since the safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied.

CareSource considers Mavenclad (cladribine) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis

DATE	ACTION/DESCRIPTION
07/02/2019	New policy for Mavenclad created.

References:

1. Mavenclad [package insert]. Rockland, MA: EMD Serono, Inc.; April, 2019.
2. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.
3. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Annals of Neurology. 2011;69(2):292-302. doi:10.1002/ana.22366.
4. FDA News Release: FDA approves new oral treatment for multiple sclerosis. www.fda.gov.
5. ClinicalTrials.gov. Identifier: NCT00725985. Oral Cladribine in Early Multiple Sclerosis (MS) (ORACLE MS). Available at: https://clinicaltrials.gov/ct2/show/NCT00725985?term=cladribine&recrs=e&rank=5.
6. ClinicalTrials.gov. Identifier: NCT00213135. A Safety and Efficacy Study of Oral Cladribine in Subjects With Relapsing-remitting Multiple Sclerosis (RRMS) (CLARITY). Available at: https://clinicaltrials.gov/ct2/show/NCT00213135?term=cladribine&recrs=e&rank=6.
7. Siddiqui, Mohd Kashif, et al. "Systematic literature review and network meta-analysis of cladribine tablets versus alternative disease-modifying treatments for relapsing–remitting multiple sclerosis." Current medical research and opinion 34.8 (2018): 1361-1371.
8. Kalincik, Tomas, et al. "Cladribine versus fingolimod, natalizumab and interferon β for multiple sclerosis." Multiple Sclerosis Journal 24.12 (2018): 1617-1626

Effective date: 09/26/2019
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