CareSource

PHARMACY POLICY STATEMENT **Ohio 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
Revised date: 07/02/2019