Commercial/Healthcare Exchange PA Criteria

Effective: August 14th, 2019

Prior Authorization: Mavenclad

Products Affected: Mavenclad (cladribine) oral tablets

Medication Description: Mavenclad is a purine antimetabolite drug used to treat relapsing forms of multiple sclerosis, relapsing-remitting diseases, and active secondary progressive diseases (SPMS). While the exact mechanism of action in which it exerts its therapeutic effects is not fully established, it is believed to have has cytotoxic effects on B and T lymphocytes by impairing DNA synthesis, leading to lymphocyte depletion. Mavenclad has a Boxed Warning indicating possible increased risks for malignancies and teratogenicity. Due to its safety profile, Mavenclad should only be used when no alternative treatments have been proven effective for the patient or if the patient has an allergic reaction to other treatments. Furthermore, this drug is not recommended for patients with clinically isolated syndrome.

Recommended cumulative dosage is 3.5mg/kg administered orally and divided into two yearly treatment courses with 1.75mg/kg per each treatment course. Each course is separated into two cycles and the first course/second cycle and second course/second cycle is administered 23 to 27 days after the last dose of the first course/first cycle and second course/first cycle, respectively. The second treatment course is administered at least 43 weeks after the last dose of the first course/second cycle. If patients are taking other oral drugs, Mavenclad administration should be separated by at least three hours.

Covered Uses: Treatment of relapsing forms of multiple sclerosis (MS), including relapsing remitting diseases and active secondary progressive disease in adults

Exclusion Criteria:

1. Patients with current malignancy
2. Pregnant women and women and men of reproductive potential who do not plan to use effective contraception during Mavenclad treatment and for 6 months after the last dose in each treatment course
3. Women intending to breastfeed on treatment day and for 10 days after last dose.
4. Patients with HIV
5. Patients with active chronic infections (e.g., hepatitis or tuberculosis)
6. Patients with a history of hypersensitivity to cladribine

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist that specializes in treatment of multiple sclerosis

Coverage Duration: 12 months

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Other Criteria:

A. Patient has a diagnosis of any of the following relapsing forms of Multiple Sclerosis:
   a. Relapsing-remitting multiple sclerosis (RRMS); OR
   b. Secondary progressive multiple sclerosis (SPMS) with documented relapses

References:

1. Mavenclad [Medication Guide]; Rockland, MA; EMD Serono, Inc.; March 2019
2. "DailyMed - MAVENCLAD- Cladribine Tablet." *U.S. National Library of Medicine*, National Institutes of Health, 2019, dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9c75e30a-a410-40f1-b653-04d532bd9144.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/13/2019

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