Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Mavenclad® (cladribine) PA Criteria FOR Multiple Sclerosis:

Mavenclad® (cladribine) is FDA-approved for the treatment of relapsing forms of multiple sclerosis (MS), including 1) relapsing-remitting disease (RRMS) and 2) active secondary progressive disease (SPMS), in those who have had an inadequate response to, or are unable to tolerate, an alternative drug indicated for MS. **Limitation of use**: Mavenclad is not indicated for *Clinically Isolated Syndrome* due to safety profile.

ICD-10 code(s):_____

Mavenclad® may be approved based on **ALL** of the following criteria:

INITIAL AUTHORIZATION: **Year 1: First treatment course - 2 cycles**

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label;

-AND-

☐ Yes ☐ No Prescribed by or in consultation with a neurologist;

-AND-

☐ Yes ☐ No Diagnosis of relapsing form of MS [e.g. relapsing-remitting MS (RRMS) or secondary progressive MS (SPMS)];

-AND-

☐ Yes ☐ No Patient does not have clinically isolated syndrome (CIS);

-AND-

☐ Yes ☐ No Patient is not pregnant/breastfeeding, HIV positive, has a current malignancy, or an active chronic infection (e.g., hepatitis or tuberculosis);

-AND-

☐ Yes ☐ No Mavenclad is not prescribed concurrently with other MS disease-modifying therapies;

-AND-

☐ Yes ☐ No Provider attests that all required baseline assessments have been completed prior to treatment initiation as described in the package insert labeling;

-AND-

☐ Yes ☐ No Trial and failure of at least two other treatments for MS that were not tolerated or ineffective. Ineffective defined as: 1 relapse in the past year, 2 or more new MRI lesions, or increased disability over a 1 year period;

-AND-

☐ Yes ☐ No First treatment course dosing* schedule is as follows:

a. First course, first treatment cycle: start any time
b. First course, second treatment cycle: administer 23 to 27 days after the last dose of the first treatment cycle

<u>REAUTHORIZATION</u>: Year 2: Second treatment course - 2 cycles.
Reauthorization will be issued for up to 1 (one) treatment course / for a total of up 2 (two) courses total in a 2 year period.

☐ Yes ☐ No Physician attestation of positive clinical response to Mavenclad therapy (e.g., decrease in: annualized relapse rate, mean number of T1 Gadolinium-enhancing (Gd+) or new and/or enlarged T2 lesions on MRI, time to disability progression, or an increase in relapse free rate, etc.);

-AND-

☐ Yes ☐ No Mavenclad is not prescribed concurrently with other MS disease-modifying therapies;

-AND-

☐ Yes ☐ No Patient is not pregnant/breastfeeding, HIV positive, has a current malignancy, or an active chronic infection (e.g., hepatitis or tuberculosis);

-AND-

☐ Yes ☐ No Second treatment course dosing* schedule is as follows:

a. Second course, <u>first</u> cycle: administer at least 43 weeks after the last dose of the first course, second cycle;
b. Second course, <u>second</u> cycle: administer 23 to 27 days after the last dose of the second treatment cycle;

-AND-

☐ Yes ☐ No Patient has not received more than 2 (two) treatment courses over 2 (two) years, divided into 4 (four) cycles, and has not exceeded the total cumulative dose per package insert;

-AND-

☐ Yes ☐ No Provider has completed all required assessments per package insert labeling prior to each treatment cycle.

***Dosing:** Dose does **NOT** exceed **<u>ANY</u>** of the following:

- 2 tablets per day
- 10 tablets per cycle
- 2 treatment cycles per course
- 1 course per year

Provider assessment monitoring criteria:

- Cancer screening, pregnancy test, CBC with lymphocytes (lymphocytes must be normal prior to first treatment course and at least 800 cells per microliter before the second treatment course), negative HIV test, tuberculosis screening, hepatitis B and C screening, presence of acute infections, vaccination with varicella zoster vaccine in those who are antibody negative, administration of other vaccinations as recommended by immunization guidelines, baseline MRI and liver function tests.
- Submission of medical records (i.e. office chart notes, lab results or other clinical information) documenting the requirements for the indications and provider monitoring criteria is **required upon request.**