Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Mayzent® (siponimod) PA Criteria FOR Multiple Sclerosis:

Mavzent® (siponimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapsing-remitting disease, (RMRS) and active secondary progressive disease, in adults.

ICD-10 code(s):_____

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

INITIAL AUTHORIZATION: 6 months

☐ 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 one of the following (a, b, or c):

a. Clinically isolated syndrome (CIS);
b. Relapsing-remitting MS (RRMS);
c. Secondary progressive MS (SPMS)];

-AND-

☐ Yes ☐ No If CIS or RRMS, patient has a trial and failure of at least two preferred MS disease-modifying therapies on the universal PDL as documented by pharmacy /medical claims. 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 Patient does not have a CYP2C9*3* genotype;

-AND

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

-AND-

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

-AND-

☐ Yes ☐ No Dose does not exceed 2 mg per day.

REAUTHORIZATION: 12 months

☐ Yes ☐ No Patient continues to be assessed as according to the package insert labeling;

-AND-

☐ Yes ☐ No Physician attestation of positive clinical response to Mayzent 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, an increase in relapse free rate, etc.);

-AND-

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

-AND-

☐ Yes ☐ No Provider has completed all required assessments prior to treatment initiation;

-AND-

☐ Yes ☐ No Dose does not exceed 2 mg per day.

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.**

Per Mayzent Package Insert labeling:

Contraindications:

- A CYP2C9*3/*3 genotype
- In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III / IV heart failure
- Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker

Assessments Prior to First Dose of Mayzent:

- Before initiation of treatment with MAYZENT, assess the following:
- CYP2C9 Genotype Determination
- Review results of a recent complete blood count
- Ophthalmic Evaluation
- Cardiac Evaluation
- Current/ Prior Medications (anti-neoplastic, immunosuppressive, or immune-modulating therapies
- Vaccinations
- Liver Function Tests