FDA INDICATIONS AND USAGE

MAYZENT® is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

APPROVAL CRITERIA

1. Patient is 18 years of age or older AND;
2. Patient has a diagnosis of relapsing MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease AND;
3. Is being prescribed by or in consultation with a neurologist or a provider that specializes in MS AND;
4. The patient has had an electrocardiogram, complete blood cell count, liver enzyme testing, and an ophthalmic evaluation, showing results deemed appropriate for treatment AND;
5. The patient has not had a myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure within the last 6 months AND;
6. The patient has no presence or history of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker AND;
7. The prescriber has performed genetic testing to rule out CYP2C9*3/*3 AND;
8. The patient has had an adequate trial and failure of at least one drug indicated for MS.

DENIAL CRITERIA

1. Patient is not 18 years of age or older OR;
2. Patient does not have a diagnosis of relapsing MS, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease OR;
3. Is not being prescribed by or in consultation with a neurologist or a physician that specializes in MS OR;
4. The patient has not had an electrocardiogram, complete blood cell count, liver enzyme testing, and an ophthalmic evaluation, showing results deemed appropriate for treatment OR;
5. The patient has had a myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure within the last 6 months OR;
6. The patient has a presence or history of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome OR;
7. The prescriber has not performed genetic testing to rule out CYP2C9*3/*3 OR;
8. The patient has not had an adequate trial and failure of at least one drug indicated for MS OR;
9. Mayzent® will concurrently be used with other MS disease modifying agents.

**CAUTIONS**

- Mayzent® may increase the risk of infection.
- Patients with a history of uveitis and patients with diabetes mellitus are at increased risk of macular edema when taking MAyzent®.
- Mayzent® may cause Bradyarrhythmia and Atrioventricular Conduction Delays
- Live attenuated vaccines should be avoided for up to 4 weeks after treatment.
- Concomitant use of moderate CYP2C9 and moderate to strong CYP3A4 inhibitors and inducers is not recommended.

**DURATION OF APPROVAL**

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

**QUANTITY LIMIT**

- 120 - 0.25mg tablets per month
- 30 – 2mg tablets per month

**REFERENCES/FOOTNOTES:**