ALASKA MEDICAID
Prior Authorization Criteria

Mayzent® (siponimod)

FDA INDICATIONS AND USAGE[1]

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[1,2]

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 with in 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 with in 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[1,2]

- 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:

1. Mayzent® (siponimod) [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corporation; March 2019. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/mayzent.pdf Accessed July 5, 2019
2. Olek, M., & Mowry, E. (June 2019) Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. In J. F. Dashe (Ed.), *UpToDate*. Retrieved July 7, 2019 from https://www.uptodate.com/contents/disease-modifying-treatment-of-relapsing-remitting-multiple-sclerosis-in-adults#H35