

ALASKA MEDICAID
Prior Authorization Criteria

**Sphingosine 1-phosphate receptor
modulators (siponimod, ponesimod,
and ozanimod)**

FDA INDICATIONS AND USAGE¹

Sphingosine 1-phosphate receptor modulators are 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. Ozanimod is also indicated for the treatment of moderately to severe ulcerative colitis.

APPROVAL CRITERIA

Multiple Sclerosis Diagnosis^{1,2,3,4,5}

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 within the last 6 months **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 patient has had an adequate trial and failure of at least two disease modifying drugs indicated for MS.

Ulcerative Colitis Diagnosis^{4,6}

1. Patient is 18 years of age or older **AND**;
2. Patient has the diagnosis of ulcerative colitis and the request is for ozanimod **AND**;
3. The medication is prescribed by or in consultation with a gastroenterologist **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 within the last 6 months **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 patient has had an adequate trial and failure of at least two systemic agents to include at least one biologic **AND**;

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DENIAL CRITERIA^{1,3,4}

1. Failure to meet approval criteria **OR;**
2. Will be used concurrently with other MS disease modifying agents **OR;**
3. Patient is pregnant **OR;**
4. Request is for ozanimod and the patient has severe sleep apnea.

CAUTIONS^{1,2,3}

- Sphingosine 1-phosphate receptor modulators 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 sphingosine 1-phosphate receptor modulators
- 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 6 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 30 days supply

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>
3. Ponvory (ponesimod) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; April 2021. Available at: <https://www.ponvory.com>. Accessed December 6, 2021.
4. Zeposia® capsules [prescribing information]. Summit, NJ: Celgene; December 2021. Available at: https://packageinserts.bms.com/pi/pi_zeposia.pdf. Accessed December 20, 2021.
5. . A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. September 2019. Available at: http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed on December 20, 2021.

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6. Feuerstein JD, Isaac s KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020;158:1450-1461.