

PHARMACY POLICY STATEMENT

HAP CareSource™ Marketplace

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|---------------------|------------------------------|
| DRUG NAME | Mayzent (siponimod) |
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Mayzent was approved by the FDA in 2019 for the treatment of relapsing forms of multiple sclerosis (MS). MS is a chronic autoimmune disease of the central nervous system that disrupts communication in the brain and between the brain and body. Mayzent is a once-daily oral sphingosine-1-phosphate (S1P) receptor modulator with high affinity for S1P receptors 1 and 5. Several assessments must be done before starting Mayzent. For example, a cardiac evaluation is needed to determine if first dose observation will be required. Genotyping is required to determine the appropriate dosage.

Mayzent (siponimod) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is 18 years of age; AND
2. Medication must be prescribed by, or in consultation with, a neurologist; AND
3. Member has a documented diagnosis of a relapsing form of MS (i.e., clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease); AND
4. Member has trial and failure of **TWO** preferred brand MS product; AND
5. The following baseline assessments have been completed (or are scheduled):
 - a) A complete blood count (CBC)
 - b) An ophthalmic evaluation
 - c) Baseline liver function tests
 - d) A cardiac evaluation by electrocardiogram (ECG) to determine if first-dose monitoring is required
 - e) CYP2C9 genotype determination; AND
6. Member has not experienced any of the following in the past 6 months: myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure; AND
7. Member does not have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker; AND
8. Mayzent will not be used concomitantly with any other disease modifying drugs for MS.
9. **Dosage allowed/Quantity limit:**
 See prescribing information for titration details.
 Maintenance dose for CYP2C9 genotype *1/*1, *1/*2, or *2/*2 = 2 mg orally once daily.
 Maintenance dose for CYP2C9 genotype *1/*3 or *2/*3 = 1 mg orally once daily.
 Note: Use in patients with CYP2C9*3/*3 genotype is contraindicated.



QL: After titration, 30 tablets per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as slowed disability progression or fewer relapses.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Mayzent (siponimod) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|---|
| 05/07/2019 | New policy created for Mayzent. |
| 10/11/2021 | Transferred to new template. General changes to language for consistency with related drugs. Updated references. Added trial of preferred alternative. PML education removed. QTc and anti-arrhythmic drug exclusions removed. Added baseline LFT. Added note about *3/*3 genotype. Added concurrent use restriction. Added renewal criteria. |
| 11/09/2022 | Added QL. |
| 09/24/2024 | Replaced trial of 1 preferred sphingosine-1-phosphate (S1P) receptor modulator with trial of TWO preferred brand MS products. |

References:

1. Mayzent [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; 2024.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in *Neurology*. 2019 Jan 8;92(2):112]. *Neurology*. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347
3. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed August 18, 2021.
4. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2
5. Roy R, Alotaibi AA, Freedman MS. Sphingosine 1-Phosphate Receptor Modulators for Multiple Sclerosis. *CNS Drugs*. 2021;35(4):385-402. doi:10.1007/s40263-021-00798-w



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Revised date: 09/24/2024