CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

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 at least 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 tried and failed or is unable to try at least 1 preferred sphingosine-1-phosphate (S1P) receptor modulator; AND
5. The following baseline assessments have been completed (or are scheduled):
   a) A complete blood count (CBC)
   b) An ophthalmic evaluation
   c) Liver function tests
   d) Skin examination
   e) A cardiac evaluation by electrocardiogram (ECG) to determine if first-dose monitoring is required
   f) CYP2C9 genotype determination to guide dosing and show the member does NOT have a CYP2C9*3/*3 genotype; 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 12 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.

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.
06/30/2025	Added skin exam as baseline assessment per label update. Specified that they cannot have a CYP2C9*3/*3 genotype (per label). Changed initial auth duration from 6 mo to 12 mo to match other policies.

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://cdn.sanity.io/files/y936aps5/production/76159995e7f4c6c0c2e6de5c4ba6a5881ab368f7.pdf. Accessed June 27, 2025.
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

Effective date: 01/01/2026
Revised date: 06/30/2025