

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Mayzent (siponimod)
BILLING CODE	Must use valid NDC
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 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) 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 (60 Td[(M)3nD]BZC9) genotype T1/*99D-2/*(e-1)8.8 (y)8a17 (in)ed (as)3.81.8 (k)-b.5.7 (un)-5.9 (l)-1 (es)-
- Note: Use in patients with CYP2C9*3/*3 genotype is contraindicated.

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

ncy with
 'ML education
 3.1 g/Ta4a1/Ta4a1/Ta4