

Drug Therapy Guidelines

Mayzent® (siponimod)

Applicable

Medical Benefit		Effective: 11/15/19
Pharmacy- Formulary 1	x	Next Review: 9/20
Pharmacy- Formulary 2	x	Date of Origin: 7/19
Pharmacy- Formulary 3/Exclusive	x	Review Dates: 6/19, 9/19
Pharmacy- Formulary 4/AON	x	

I. Medication Description

Mayzent is a sphingosine 1-phosphate receptor modulator and binds with high affinity to S1P receptors 1 and 5. Mayzent blocks the capacity of lymphocytes to exit the lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which Mayzent exerts therapeutic effects in multiple sclerosis is unknown, but may involve reduction of lymphocyte migration into the central nervous system.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Mayzent is available when the following criteria are met:

- Member has a diagnosis of a relapsing form of multiple sclerosis (MS) including clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS) or active secondary progressive disease (SPMS) **AND**
- Medication is prescribed by or in consultation with a neurologist **AND**
- Member is at least 18 years of age **AND**
- Results of CYP2C9 genotype testing are supplied (Note: coverage is not available for members with CYP2C9*3/*3 genotype) **AND**
 - The requested maintenance dose is 2mg daily for members with the following genotypes: CYP2C9*1/*1, CYP2C9*1/*2, or CYP2C9*2/*2 **OR**
 - The requested maintenance dose is 1mg daily for members with the following genotypes: CYP2C9*1/*3 or CYP2C9*2/*3

IV. Quantity Limitations

- Mayzent 0.25mg tablets: 112 tablets per 28 days
- Mayzent 2mg tablets: 30 tablets per 30 days

V. Coverage Duration

Initial coverage is provided for 6 months and may be renewed in up to 12 month intervals.

VI. Coverage Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Mayzent is available as 0.25mg and 2mg oral tablets.

VIII. Summary of Policy Changes

- 7/15/19: new policy
- 11/15/19: no policy changes

IX. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. URL: <http://clinicalpharmacology.com> . Updated August 2019.
2. Mayzent [prescribing information]. East Hanover, New Jersey 07936: Novartis Pharmaceuticals Corporation; Revised 3/2019.
3. UpToDate [database online]. Waltham, MA: UpToDate, Inc.; 2019 URL: <https://www.uptodate.com> . Updated August 2019.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.