BlueCross BlueShield
Federal Employee Program

MAYZENT
(siponimod)

Preferred product: Mayzent

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

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

Regulatory Status

FDA-approved indication: Mayzent is a sphingosine-1-phosphate receptor modulator 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. Before therapy with Mayzent is initiated, a recent (i.e., within 6 months or after discontinuation of prior therapy) complete blood count (CBC) should be reviewed (1).

Mayzent causes a dose-dependent reduction in peripheral lymphocyte count to 20-30% of baseline values because of reversible sequestration of lymphocytes in lymphoid tissues. As a result, Mayzent may therefore increase the risk of infections (1).

Mayzent is contraindicated: (1)

- In patients with a CYP2C9*3/*3 genotype.
- In patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
- In patients who have a presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker.

After the initial titration is complete, if Mayzent treatment is interrupted for 4 or more consecutive daily doses, reinitiated treatment with Day 1 of the titration regimen (1).

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If patients are taking antineoplastic, immunosuppressive or immune modulating therapies, or if there is a history of prior use of these drugs, possible additive immunosuppressive effects should be considered before starting treatment with Mayzent (1).

Live, attenuated vaccines are generally not recommended for a person with MS because their ability to cause disease has been weakened but not totally inactivated. The use of live attenuated vaccines should be avoided while patients are taking Mayzent and for 4 weeks after stopping treatment (1-2).

The safety and effectiveness of Mayzent in pediatric patients less than 18 years of age have not been established (1).

Summary

Mayzent (siponimod) is a sphingosine-1-phosphate-receptor (S1P) modulator that binds with high affinity to S1P receptors 1 and 5. Mayzent blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which siponimod exerts therapeutic effects in multiple sclerosis (MS) is unknown but may involve reduction of lymphocyte migration into the central nervous system. The safety and effectiveness of Mayzent in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Mayzent while maintaining optimal therapeutic outcomes.

References

1. Mayzent [package insert, East Hanover, NJ: Novartis Pharmaceuticals Corporation; Jube 2024.
2. Cahill JF, Izzo A, Garg N. Immunization in patients with multiple sclerosis. Neurological Bulletin. 2010;2(1):17-21.