BlueCross BlueShield
Federal Employee Program

Gilenya **(fingolimod),** Tascenso ODT (fingolimod)

Preferred product: fingolimod

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Gilenya and Tascenso ODT (fingolimod) are sphingosine-1-phosphate-receptor (S1PR) modulator that binds to receptors in the body that block progression of lymphocytes (white blood cells) into the blood and may reduce the movement of lymphocytes into the central nervous system. Although the exact mechanism of action in Multiple Sclerosis (MS) is unknown, it is thought that through this inhibition, lymphocytes are unable to destroy the myelin sheath which leads to lesions that are characteristic of MS and reducing the severity of MS (1-2).

Gilenya and Tascenso ODT are indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability (1-2).

Regulatory Status

FDA-approved indications: (1-2)

- Gilenya 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 patients 10 years of age and older.
- Tascenso ODT 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 patients 10 years of age and older.

Patients with some pre-existing conditions (e.g., ischemic heart disease, history of myocardial infarction, congestive heart failure, history of cardiac arrest, cerebrovascular disease, history of symptomatic bradycardia, history of recurrent syncope, severe untreated sleep apnea, AV block, sino-atrial heart block) may poorly tolerate the Gilenya/Tascenso ODT-induced bradycardia, or experience serious rhythm disturbances after the first dose. Prior to treatment with Gilenya or Tascenso ODT, patients should have a cardiac evaluation by a physician

Gilenya **(fingolimod),** Tascenso ODT (fingolimod)

Preferred product: fingolimod

appropriately trained to conduct such evaluation, and if treated with Gilenya or Tascenso ODT, after the first dose patients should be monitored for 6 hours for signs and symptoms of bradycardia with hourly pulse and blood pressure measurement and overnight with continuous ECG in a medical facility (1-2).

Gilenya and Tascenso ODT are contraindicated in patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, baseline QT interval ≥500 ms, or Class III/IV heart failure (1-2).

Gilenya and Tascenso ODT are contraindicated in patients with Mobitz Type II 2nd degree or 3rd degree AV block, a prolonged QTc interval or at risk for QT prolongation, or concomitant use of Class Ia or Class III anti-arrhythmic drugs (1-2).

If Gilenya or Tascenso ODT therapy is discontinued for more than 14 days, after the first month of treatment, the effects on heart rate and AV conduction may recur on reintroduction of treatment and the same precautions (first dose monitoring) as for initial dosing should apply. Within the first 2 weeks of treatment, first dose procedures are recommended after interruption of one day or more, during week 3 and 4 of treatment first dose procedures are recommended after treatment interruption of more than 7 days (1-2).

Before initiating treatment with Gilenya or Tascenso ODT, a recent CBC should be available due to the increased risk of infection. Macular edema may occur in patients receiving Gilenya or Tascenso ODT and therefore an ophthalmologic evaluation should be performed at baseline and 3 to 4 months after initiation of treatment; patients with diabetes with a history of uveitis are at increased risk. Elevations of liver enzymes may occur in patients and a recent transaminase and bilirubin level should be done before initiation of therapy. Gilenya and Tascenso ODT may cause a decrease in pulmonary function tests and spirometry and diffusion lung capacity for carbon monoxide should be obtained with clinically indicated. Gilenya and Tascenso ODT should be used during pregnancy only if the potential benefit justifies the potential risk to the

Gilenya **(fingolimod),** Tascenso ODT (fingolimod)

Preferred product: fingolimod

fetus (1-2).

Gilenya and Tascenso ODT have not been administered concomitantly with antineoplastic, immunosuppressive, or immune modulating therapies used for treatment of MS. Concomitant use of Gilenya or Tascenso ODT with any of these therapies would be expected to increase the risk of immunosuppression (1-2).

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 (3).

The safety and effectiveness in pediatric patients with MS below the age of 10 have not been established (1-2).

Summary

Gilenya and Tascenso ODT (fingolimod) are indicated in the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. The first dose of Gilenya or Tascenso ODT should be administered in a setting in which resources to appropriately observe and manage symptomatic bradycardia are available. Gilenya and Tascenso ODT are contraindicated in patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure or Class III/IV heart failure. Gilenya and Tascenso ODT are also contraindicated in patients with Mobitz Type II 2nd degree or 3rd degree AV block. The safety and effectiveness in pediatric patients with MS below the age of 10 have not been established (1-2).

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

References

BlueCross BlueShield
Federal Employee Program

Gilenya **(fingolimod),** Tascenso ODT (fingolimod)

Preferred product: fingolimod

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. Tascenso ODT [package insert]. San Jose, CA: Handa Neuroscience, LLC; June 2024.
3. Cahill JF, Izzo A, Garg N. Immunization in patients with multiple sclerosis. Neurological Bulletin. 2010;2(1):17-21.