Pharmacy Policy Bulletin: J-0135 Fingolimod – Commercial and Healthcare Reform	
Number: J-0135	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0135-023	**Original Date:** 12/10/2010
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Gilenya (fingolimod) • Tascenso ODT (fingolimod)

FDA-Approved Indication(s):	• Gilenya
	  ○ 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. The 0.25 mg capsule is indicated for use in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg. The 0.5 mg capsule is indicated for use in adults and pediatric patients 10 years of age and older and weighing more than 40 kg.
	• Tascenso ODT
	  ○ 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. The 0.25 mg tablet is indicated for use in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg. The 0.5 mg tablet is indicated for use in adults and pediatric patients 10 years of age and older and weighing more than 40 kg.

Background:	• Fingolimod is a sphingosine 1-phosphate (S1P) receptor modulator that works by binding to S1P receptors. Fingolimod blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which fingolimod exerts therapeutic effects in multiple sclerosis is unknown but may involve reduction of lymphocyte migration into the central nervous system (CNS). • Clinically isolated syndrome is the first episode of neurological symptoms caused by inflammation and demyelination in the CNS. Relapsing-remitting MS (RRMS) is characterized by clearly defined attacks of new or increasing neurologic symptoms. The attacks are followed by periods of partial or complete recovery (remissions). Secondary progressive disease follows an initial relapsing remitting course, with disability gradually increasing over time.

	• Prescribing Considerations: ○ Fingolimod should be prescribed under the supervision of a neurologist. ○ All patients must be observed for bradycardia for 6 hours after the first dose including re-initiation after discontinuation greater than 14 days and dose increases. ○ Fingolimod is contraindicated in patients with recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, Class III/IV heart failure, baseline QTc interval ≥ 500 msec, cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs, and history of Mobitz Type II 2nd or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. ○ Fingolimod has warnings and precautions for infections, progressive multifocal leukoencephalopathy (PML), macular edema, liver injury, posterior reversible encephalopathy syndrome (PRES), respiratory effects, fetal risk, severe increase in disability after stopping fingolimod, tumefactive MS, increased blood pressure, and malignancies. ○ Assessments are required prior to initiating fingolimod, including first-dose monitoring, electrocardiogram, complete blood count, ophthalmic evaluation, and liver function tests. Additionally, respiratory function should be evaluated when clinically indicated, blood pressure should be monitored during treatment, and suspicious skin lesions should be evaluated.

Approval Criteria

I. Initial Authorization

A. Gilenya 0.25 mg

When a benefit, coverage of Gilenya 0.25 mg may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member is 10 to 17 years of age.
2. The member weighs ≤ 40 kg.
3. The member has a diagnosis of MS (ICD-10: G35), classified as one (1) of the following relapsing forms **(a., b., or c.)**:
  a. Clinically isolated syndrome
  b. Relapsing-remitting disease
  c. Active secondary progressive disease

B. Gilenya (fingolimod) 0.5 mg

When a benefit, coverage of Gilenya (fingolimod) 0.5 mg may be approved when all of the following criteria are met: **(1. through 4.):**

1. The member is 10 years of age or older.
2. The member weighs > than 40 kg.
3. The member has a diagnosis of MS (ICD-10: G35), classified as one (1) of the following relapsing forms **(a., b., or c.):**
  a. Clinically isolated syndrome
  b. Relapsing-remitting disease
  c. Active secondary progressive disease
4. If the request is for brand Gilenya, the member has experienced therapeutic failure or intolerance to generic fingolimod.

C. Tascenso ODT 0.25 mg

When a benefit, coverage of Tascenso ODT 0.25 mg may be approved when all of the following criteria are met **(1., 2., and 3.):**

1. The member is 10 to 17 years of age.
2. The member weighs ≤ 40 kg.
3. The member has a diagnosis of MS (ICD-10: G35), classified as one (1) of the following relapsing forms **(a., b., or c.):**
   a. Clinically isolated syndrome
   b. Relapsing-remitting disease
   c. Active secondary progressive disease

D. Tascenso ODT 0.5 mg

When a benefit, coverage of Tascenso ODT 0.5 mg may be approved when all of the following criteria are met **(1. through 4.):**

1. The member is 10 years of age or older.
2. The member weighs > 40 kg.
3. The member has a diagnosis of MS (ICD-10: G35), classified as one (1) of the following relapsing forms **(a., b., or c.):**
   a. Clinically isolated syndrome
   b. Relapsing-remitting syndrome
   c. Active secondary progressive disease
4. The member meets one (1) of the following **(a. or b.):**
   a. The member has experienced therapeutic failure or intolerance to plan-preferred generic fingolimod capsules.
   b. The member has an inability to swallow capsules.

II. Reauthorization

A. Gilenya 0.25 mg

When a benefit, reauthorization of Gilenya 0.25 mg may be approved when the following criteria are met **(1., 2., and 3.)**:

1. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(a., b., or c.)**:
   a. Disease stability
   b. Disease improvement
   c. Delayed disease progression
2. The member is 10 to 17 years of age.
3. The member weighs ≤ 40 kg.

B. Gilenya (fingolimod) 0.5 mg

When a benefit, reauthorization of Gilenya (fingolimod) 0.5 mg may be approved when the following criteria are met **(1. and 2.):**

1. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(a., b., or c.):**
   a. Disease stability
   b. Disease improvement
   c. Delayed disease progression
2. If the request is for brand Gilenya, the member has experienced therapeutic failure or intolerance to generic fingolimod.

C. Tascenso ODT 0.25 mg

When a benefit, reauthorization of Tascenso ODT 0.25 mg may be approved when the following criteria are met **(1., 2., and 3.):**

1. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(a., b., or c.):**
   a. Disease stability
   b. Disease improvement
   c. Delayed disease progression

2. The member is 10 to 17 years of age.
3. The member weighs ≤ 40 kg.

D. Tascenso ODT 0.5 mg

When a benefit, reauthorization of Tascenso ODT 0.5 mg may be approved when all of the following criteria are met **(1. and 2.):**

1. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(a., b., or c.):**
   - **a.** Disease stability
   - **b.** Disease improvement
   - **c.** Delayed disease progression
2. The member meets one (1) of the following **(a. or b)**:
   - **a.** The member has experienced therapeutic failure or intolerance to plan-preferred generic fingolimod capsules.
   - **b.** The member has an inability to swallow capsules.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Combination use of disease modifying MS agents (e.g., Aubagio [teriflunomide], interferons, Copaxone [glatiramer], Tysabri [natalizumab], etc.) will not be authorized.

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 24 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. Tascenso ODT [package insert]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd.; June 2024.
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. *Neurol*. 2018 April 24;90(17):1-228.
4. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed January 27, 2025.