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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	June 7, 2012
Subject:	Gilenya Tascenso ODT	**Page:**	1 of 10

Last Review Date: December 12, 2025

Gilenya Tascenso ODT

Description

Gilenya (fingolimod), Tascenso ODT (fingolimod)

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 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 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).

Related policies
Acthar Gel, Ampyra, Aubagio, Kesimpta, Lemtrada, Mavenclad, Mayzent, MS Injectables, Ocrevus, Ponvory, Tecfidera, Tysabri, Zeposia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Gilenya/Tascenso ODT may be considered **medically necessary** if the conditions indicated below are met.

Gilenya/Tascenso ODT may be considered **investigational** for all other indications.

Prior-Approval Requirements

Fingolimod and Tascenso ODT only

Age 10 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Member must be observed for 6 hours after the first dose for signs and symptoms of bradycardia with hourly pulse and blood pressure measurements and an ECG prior to dosing and at the end of the observation period
2. Prescriber has reviewed baseline complete blood count (CBC) including lymphocyte count
3. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
4. **NO** history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
5. **NO** significant QTc prolongation (QTc greater than or equal to 500 msec)
6. Patients with a history of uveitis and/or diabetes **ONLY**: will have an ophthalmic evaluation of the fundus, including the macula, prior to initiation of therapy
7. **NO** concurrent use with other MS disease modifying agents
8. **NOT** given concurrently with live vaccines
9. **Tascenso ODT only**: Patient is unable to swallow or has difficulty swallowing capsules

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Gilenya only

Age 10 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following with provided documentation (e.g., medical records, laboratory reports):

1. Member must be observed for 6 hours after the first dose for signs and symptoms of bradycardia with hourly pulse and blood pressure measurements and an ECG prior to dosing and at the end of the observation period
2. Prescriber has reviewed baseline complete blood count (CBC) including lymphocyte count
3. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
4. **NO** history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
5. **NO** significant QTc prolongation (QTc greater than or equal to 500 msec)
6. Patients with a history of uveitis and/or diabetes **ONLY**: will have an ophthalmic evaluation of the fundus, including the macula, prior to initiation of therapy
7. **NO** concurrent use with other MS disease modifying agents
8. **NOT** given concurrently with live vaccines
9. **Age 10-17**: Patient **MUST** have tried fingolimod (generic Gilenya) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
10. **Age 18+**: Patient **MUST** have tried the preferred product(s) (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Fingolimod and Tascenso ODT only

Age 10 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
2. **NO** history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
3. **NO** significant QTc prolongation (QTc greater than or equal to 500 msec)
4. **NO** concurrent use with other MS disease modifying agents
5. **NOT** given concurrently with live vaccines

Gilenya only

Age 10 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following with provided documentation (e.g., medical records, laboratory reports:

1. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
2. **NO** history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
3. **NO** significant QTc prolongation (QTc greater than or equal to 500 msec)
4. **NO** concurrent use with other MS disease modifying agents
5. **NOT** given concurrently with live vaccines

6. **Age 10-17**: Patient **MUST** have tried fingolimod (generic Gilenya) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
7. **Age 18+**: Patient **MUST** have tried the preferred product(s) (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication/Strength	Quantity Limit
Gilenya 0.25 mg capsule	90 units per 90 days **OR**
Gilenya 0.5 mg capsule	90 units per 90 days **OR**
Tascenso 0.25 mg ODT	90 units per 90 days
Tascenso 0.5 mg ODT	

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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

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

Policy History

Date	Action
April 2012	New PA policy
March 2013	Annual editorial review and reference update Addition to criteria that the patient must not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome; unless patient has a pacemaker. Added no concurrent therapy with Class Ia or Class III anti-arrhythmic drugs.
September 2013	Annual editorial review and reference update
December 2014	Annual editorial review and reference update. Removal of “not being treated with Class Ia and Class III anti-arrhythmics” and examples from criteria of other MS disease modifying agents
February 2015	Change in PA Allowance from 84 caps per 84 days to accommodate new packaging of 30 count
March 2015	Annual editorial review and reference update
September 2016	Annual editorial review. Reference update. Policy code changed from 5.07.08 to 5.60.08
December 2016	Annual editorial review and reference update Addition of not given concurrently with live vaccines

March 2017	Annual review
June 2017	Annual review
June 2018	Decrease in age to 10 years of age and older. Addition of 0.25 mg strength
September 2018	Annual review
September 2019	Annual review and reference update
December 2019	Revised relapsing MS indication to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
March 2020	Annual review and reference update
April 2020	Added statement that Gilenya is a preferred product
June 2020	Annual review
September 2020	Annual review. Addition of requirements per SME: obtain CBC and lymphocyte count prior to initiation of therapy, no significant QTc prolongation; ophthalmic evaluation prior to therapy for patients with a history of uveitis and/or diabetes
December 2020	Annual review
June 2021	Annual review
June 2022	Annual editorial review and reference update
December 2022	Annual review. Addition of Tascenso ODT to policy. Changed policy number to 5.60.008. Removed Gilenya 0.25mg from policy due to no product availability
January 2023	Added Medex requirement for brand Gilenya and added Appendix 1
February 2023	Added Tascenso 0.5mg ODT to policy
March 2023	Annual review. Added Gilenya 0.25mg capsule to policy
June 2023	Annual review
December 2023	Annual review and reference update
June 2024	Annual review
December 2024	Annual review and reference update
March 2025	Annual review and reference update
December 2025	Annual review. Removed list of injectable MS medications from Appendix and removed that patient must t/f fingolimod for adults. Added documentation requirement for non-preferred medication

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_ProductMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists