

PHARMACY POLICY STATEMENT

Marketplace

| | |
|------------------|---|
| DRUG NAME | Fingolimod (Gilenya, Tascenso ODT) |
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Gilenya was initially approved by the FDA in 2010. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS). It was the first oral drug approved for MS and later became the first drug approved for MS in the pediatric population. MS is a chronic autoimmune disease of the central nervous system that disrupts communication in the brain and between the brain and body. Gilenya was the first sphingosine-1-phosphate (S1P) receptor modulator. It requires all patients to be monitored for 6 hours after the first dose is given due to the potential for bradycardia. Tascenso ODT is a 505 (b)(2) product of Gilenya.

Fingolimod will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 10 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of a relapsing form of MS (i.e., clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease); AND
4. Member must have trial and failure of **TWO** brand MS products; AND
5. The following baseline assessments have been completed (or are scheduled):
 - a) A complete blood count (CBC)
 - b) An ophthalmic evaluation
 - c) Baseline QTc interval is less than 500 msec
 - d) Baseline liver function tests; AND
6. The risk of progressive multifocal leukoencephalopathy (PML) has been discussed; AND
7. Member has not experienced any of the following in the past 6 months: Myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure; AND
8. Member does not have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker; AND
9. Fingolimod will not be used concomitantly with any other disease modifying drugs for MS; AND
10. **Dosage allowed/Quantity limit:**
 Adults and pediatrics 10 years of age and older weighing more than 40 kg: 0.5 mg once daily
 Pediatrics 10 years of age and older weighing less than or equal to 40 kg: 0.25 mg once daily
 QL: 30 capsules/tablets per 30 days

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as fewer relapses or no new or enlarging lesions on MRI.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers fingolimod not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|---|
| 06/12/2017 | New policy for Gilenya created. Not covered diagnosis added. Contraindications added in criteria. Baseline QTc interval required |
| 12/06/2017 | Age coverage expanded. Confirmation of diagnosis based on McDonald criteria is no longer required. |
| 09/13/2018 | Age coverage expanded into pediatric population. CBC baseline and suggested discussion with member about PML risks prior to treatment were added to criteria. |
| 10/12/2021 | Transferred to new template. General changes to language for consistency with related drugs. Updated references. Removed CIS from exclusion list and added to criteria. Moved ophthalmic note into the criteria. Added baseline LFT's. Added note regarding concomitant use. Added pediatric dosing. Added renewal criteria. Removed anti-arrhythmic exclusion, could be ok if they have cardiac consult. |
| 11/09/2022 | Renamed policy as generic name and added Tascenso ODT (505b2) to policy. Added reference for pediatric MS. Added QL. |
| 04/19/2023 | Removed restriction for Tascenso only being for those under 40 kg. |
| 09/24/2024 | Replaced trial and failure of Gilenya, or inability to swallow capsules for Tascenso ODT requests with trial of any TWO brand MS products for both Tascenso ODT and Gilenya |

References:

- Gilenya [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Inc., 2024.
- Tascenso ODT [prescribing information]. Cycle Pharmaceuticals Ltd; 2024.
- Kappos L, et al. A placebo-controlled trial of oral fingolimod in relapsing multiple sclerosis. *N Engl J Med*. 2010 Feb 4;362(5):387-401.
- Cohen JA, et al. Oral fingolimod or intramuscular interferon for relapsing multiple sclerosis. *N Engl J Med*. 2010 Feb 4;362(5):402-15.
- Calabresi PA, et al. Safety and efficacy of fingolimod in patients with relapsing-remitting multiple sclerosis (FREEDOMS II): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2014 Jun;13(6):545-56.
- Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in *Neurology*. 2019 Jan 8;92(2):112]. *Neurology*. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347
- National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed August 18, 2021.
- Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2
- Roy R, Alotaibi AA, Freedman MS. Sphingosine 1-Phosphate Receptor Modulators for Multiple Sclerosis. *CNS Drugs*. 2021;35(4):385-402. doi:10.1007/s40263-021-00798-w
- Chitnis T, Arnold DL, Banwell B, et al. Trial of Fingolimod versus Interferon Beta-1a in Pediatric Multiple Sclerosis. *N Engl J Med*. 2018;379(11):1017-1027. doi:10.1056/NEJMoa1800149
- La Mantia L, Tramacere I, Firwana B, Pacchetti I, Palumbo R, Filippini G. Fingolimod for relapsing-remitting multiple sclerosis. *Cochrane Database Syst Rev*. 2016;4:CD009371. Published 2016 Apr 19. doi:10.1002/14651858.CD009371.pub2
- Tramacere I, Del Giovane C, Salanti G, D'Amico R, Filippini G. Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis. *Cochrane Database Syst Rev*. 2015;(9):CD011381. Published 2015 Sep 18. doi:10.1002/14651858.CD011381.pub2
- Filippini G, Del Giovane C, Clerico M, et al. Treatment with disease-modifying drugs for people with a first clinical attack suggestive of multiple sclerosis. *Cochrane Database Syst Rev*. 2017;4(4):CD012200. Published 2017 Apr 25. doi:10.1002/14651858.CD012200.pub2

14. Jakimovski D, Awan S, Eckert SP, Farooq O, Weinstock-Guttman B. Multiple Sclerosis in Children: Differential Diagnosis, Prognosis, and Disease-Modifying Treatment. *CNS Drugs*. 2022;36(1):45-59. doi:10.1007/s40263-021-00887-w

Effective date: 01/01/2025

Revised date: 09/24/2024