



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 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.

References:

1. Gilenya [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Inc., 2019.
2. Tascenso ODT [prescribing information]. Cycle Pharmaceuticals Ltd; 2022.
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4. Cohen JA, et al. Oral fingolimod or intramuscular interferon for relapsing multiple sclerosis. *N Engl J Med*. 2010 Feb 4;362(5):402-15.
5. 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.
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7. 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](https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf). Accessed August 18, 2021.
8. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*

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13. 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

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