Insurance Co Name

Insurance Co Address

Date

Re: Name: Patient Name

DOB: Enter date of birth

Account #: Enter insurance company account number

To Whom It May Concern:

This letter is to support an appeal for choose a reason Gilenya® (fingolimod) for my patient, enter patient namefor the management of choose his/her multiple sclerosis. You have denied coverage for this treatment because insert reason from denial letter here.

Enter patient name has been treated with insert previous therapies used and reasons for discontinuing here.

Gilenya is medically necessary for my patient because insert rationale here. This is supported by the American Academy of Neurology Practice Guideline recommendation [enter appropriate recommendation here.](https://www.aan.com/Guidelines/home/GetGuidelineContent/900) Additionally, my patient has completed insert screening test and results here, for example Hep B or JCV status.

Gilenya is a sphingosine 1 phosphate receptor modulator and thought to induce some immune cells to remain in the lymph nodes, inhibiting them from migrating in to the brain and spinal cord. Gilenya received market approval from the US Food and Drug Administration (FDA) in October 2010 for the treatment of relapsing forms of MS in adults. In 2018, the FDA approved the use of Gilenya is pediatric patients age 10 and older with relapsing forms of MS.

In a two-year phase III trial known as FREEDOMS involving 1,272 people with relapsing-remitting MS, fingolimod significantly reduced relapse rates (the primary endpoint of the study) and slowed disability progression (a secondary endpoint) when compared to inactive placebo.1 In a second one-year clinical trial, called the TRANSFORMS study, comparing two different doses of fingolimod with Avonex® (interferon beta-1a, 30mcg IM once weekly) involving 1,292 individuals with relapsing-remitting MS, both doses of fingolimod significantly reduced relapse rates (the primary endpoint of the study) and disease activity on brain MRI in comparison to the group taking interferon beta-1a.2

Please refer to the consensus paper by the [Multiple Sclerosis Coalition entitled The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence](http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color) for evidence in support of early and ongoing access to the full range of therapy options for patients with MS.3

[The American Academy of Neurology Practice Guideline: Disease-modifying therapies for Adults with Multiple Sclerosis](https://www.aan.com/Guidelines/home/GetGuidelineContent/900) states that starting therapy with an approved disease modifying therapy is an effective strategy to reduce relapses and MRI activity. Additionally, the guideline describes various reasons for the need to switch therapy, including non-adherence, breakthrough disease (switch to an agent with a different MoA), adverse events, or contraindications to the current therapy.4

Gilenya is medically necessary for my patient, enter patient name. I respectfully request that you choose consider/reconsider. coverage for this patient. Thank you in advance for your timely response.

Sincerely,

Click or tap here to enter text.

Click or tap here to enter text.

Click or tap here to enter text.

1 Kappos L, Radue EW, O'Connor P, Polman C, Hohlfeld R, Calabresi P, Selmaj K, Agoropoulou C, Leyk M, Zhang-Auberson L, Burtin P; FREEDOMS Study Group, A placebo-controlled trial of oral fingolimod in relapsing multiple sclerosis, N Engl J Med. 2010 Feb 4;362(5):387-40.

2 Cohen JA, Barkhof F, Comi G, Hartung HP, Khatri BO, Montalban X, Pelletier J, Capra R, Gallo P, Izquierdo G, Tiel-Wilck K, de Vera A, Jin J, Stites T, Wu S, Aradhye S, Kappos L; TRANSFORMS Study Group, Oral fingolimod or intramuscular interferon for relapsing multiple sclerosis, N Engl J Med. 2010 Feb 4;362(5):402-15.

3 Costello K and Kalb R. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. Consensus Paper by the Multiple Sclerosis Coalition. 2018.

4 Rae-Grant A, Day GS, Marrie RA, Rabinstein A, Cree BAC, Gronseth GS, Haboubi M, Halper J, Hosey JP, Jones DE, Lisak R, Pelletier D, Potrebic S, Sitcov C, Sommers R, Stachowiak J, Getchius TSD, Merillat SA, Pringsheim T.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. Neurology. 2018 Apr 24; 90(17):777-788.