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 Mavenclad® (cladribine) 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.

Mavenclad 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.

Mavenclad’s mechanism of action is thought to involve cytotoxic effects on B and T lymphocytes through impairment of DNA synthesis resulting in depletion of lymphocytes. Mavenclad received market approval from the US Food and Drug Administration (FDA) in March 2019 for the treatment of relapsing forms of MS, to include relapsing-remitting disease and active secondary progressive disease, in adults.

The efficacy of Mavenclad was demonstrated in a 96-week randomized, double-blind, placebo-controlled clinical trial of 1, 326 patients with relapsing forms of MS known as the CLARITY trial. In this trial Mavenclad reduced the annualized relapse rate by 58% compared to those taking placebo. During the 96-week trial, 81% of those treated with Mavenclad remained relapse free compared to 63% of those treated with placebo.1

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.2

[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.3

Mavenclad 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 Giovannoni G, Comi G, Cook S, Rammohan K, Rieckmann P, Soelberg Sorensen P, Vermersch P, Chang P, Hamlett A, Musch B, Greenberg SJ; CLARITY Study Group. A placebo-controlled trial of oral cladribine for relapsing multiple sclerosis. N Engl J Med. 2010 Feb 4; 362(5):416-426.

2 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.

3 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-modifyingtherapies 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.