Insurance Co Name

Insurance Co Address

August 11, 2023

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 Choose an item. for my patient, enter patient namefor the management of 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.

Choose an item. is medically necessary for my patient because insert rationale. 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.

Although MS is not among the conditions for which Rituxan has received US Food and Drug Administration (FDA) approval for marketing, a growing body of evidence supports its safe and efficacious use in certain patients with MS. Rituxan depletes both normal and malignant B cells that have a CD20 molecule on their surfaces and is therefore used to treat diseases which are characterized by having too many B cells, overactive B cells, or dysfunctional B cells. This includes many lymphoma, leukemia, transplant rejection and auto-immune

disorders. At present, it is FDA approved for the treatment of non-Hodgkin’s lymphoma, chronic

lymphocytic leukemia, rheumatoid arthritis and certain forms of granulomatosis. A [2013 systematic review](https://www.ncbi.nlm.nih.gov/pubmed/23843952) discusses the results of four studies involving 599 participants with MS.1 These studies collectively demonstrated that Rituxan was safe, reduced relapse rates and reduced disease activity on brain MRI.

[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.2

A recent study published in *Lancet Neurology* in 2022 detailed a randomized, controlled trial comparing rituximab versus dimethyl fumarate for patients with relapsing remitting MS. There were significant differences in the rate of relapse, with 3% of patients on rituximab experiencing a protocol-defined relapse, versus 16% in the dimethyl fumarate group. 3

Choose an item. 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 Castillo-Trivino T, Braithwaite D, Bacchetti P, Waubant E (2013) Rituximab in Relapsing and Progressive Forms of Multiple Sclerosis: A Systematic Review. PLoS ONE 8(7): e66308. doi:10.1371/journal.pone.0066308.

2 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.

3 Svenningsson A, Frisell T, Burman J, Salzer J, Fink K, Hallberg S, Hambraeus J, Axelsson M, Nimer FA, Sundström P, Gunnarsson M, Johansson R, Mellergård J, Rosenstein I, Ayad A, Sjöblom I, Risedal A, de Flon P, Gilland E, Lindeberg J, Shawket F, Piehl F, Lycke J. Safety and efficacy of rituximab versus dimethyl fumarate in patients with relapsing-remitting multiple sclerosis or clinically isolated syndrome in Sweden: a rater-blinded, phase 3, randomised controlled trial. Lancet Neurol. 2022 Aug;21(8):693-703.