Insurance Co Name

Insurance Co Address

July 30, 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 Briumvi® (ublituximab) 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.

Briumvi 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.

Briumvi is a CD20-directed cytolytic antibody that is presumed to work by binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, ublituximab results in antibody-dependent cellular cytolysis and complement-mediated lysis. It was approved by the US Food and Drug Administration (FDA) for the treatment of adult patients with relapsing forms of multiple sclerosis in 2022.

In the ULTIMATE I and ULTIMATE II studies included 1,094 people with a relapsing form of MS, which compared Briumvi to teriflunomide (Aubagio®), Briumvi significantly reduced the annualized relapse rate by up to 59% compared with Aubagio over two years in people with relapsing MS. In addition, Briumvi significantly delayed confirmed progression of disability on the estimated disability status scale (EDSS) by up to 34% compared with Aubagio. No Evidence of Disease Activity (NEDA) was achieved in 43-45% of those on Briumvi compared with 11-15% for those on Aubagio. Briumvi also significantly reduced the number of enhancing lesions observed on MRI by up to 97% compared with Aubagio. i

[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. ii

Briumvi 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.

i Steinman and the ULTIMATE I and II investigators, *Ublituximab versus Teriflunomide in Relapsing Multiple Sclerosis.* N Engl J Med 2022; 387(8):704-714, August 25, 2022.

ii 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.