Insurance Co Name

Insurance Co Address

February 14, 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 Kesimpta® (ofatumumab) 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.

Kesimpta 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.

KESIMPTA 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, ofatumumab results in antibody-dependent cellular cytolysis and complement-mediated lysis. It was approved in 2020 by the US Food and Drug Administration (FDA) for the treatment of adult patients with relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

The safety and efficacy of Kesimpta when compared to teriflunomide was demonstrated in two Phase III studies, ASCLEPIOS I and ASCLEPIOS II. The studies involved 615 people who were recently diagnosed with relapsing forms of MS and who were treatment naïve. These studies compared Kesimpta to teriflunomide. In both studies, Kesimpta significantly lowered the annualized relapse rate compared to teriflunomide by 51% and 59%, delayed 3-month and 6-month confirmed disability progression compared to teriflunomide with a risk reduction of 34% and 32%, showed significant, near-complete suppression of Gd+ T1 inflammatory lesions compared to teriflunomide with a relative reduction of 98% and 94%, showed significant reduction in the number of new or enlarging T2 lesions with a relative reduction of 82% and 85%. Post-hoc analysis of the Asclepios I and II data showed achievement of NEDA-3 (no evidence of disease activity) in 47% of patients in the Kesimpta group in months 0-12 vs 25% of patients in the teriflunomide group; in months 12-24, 88% of patients in the Kesimpta group achieved NEDA vs 48% in the teriflunomide group.i, ii

[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 treatment with an approved disease modifying therapy (DMT) 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. iii Continuity of care with a disease-modifying therapy is key to preventing disease progression.

Kesimpta 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 [Gartner J, Hauser SL, Bar-Or A, Montalban X, Cohen JA, Cross AH, Deiva K, Ganjgahi H, Haring DA, Li B, Pingili R, Ramanathan K, Su W, Willi R, Kieseier B, Kappos L. Efficacy and safety of ofatumumab in recently diagnosed, treatment-naive patients with multiple sclerosis: Results from ASCLEPIOS I and II. Mult Scler. 2022 Sep;28(10):1562-1575. doi: 10.1177/13524585221078825. Epub 2022 Mar 10.](https://clinicaltrials.gov/ct2/bye/rQoPWwoRrXS9-i-wudNgpQDxudhWudNzlXNiZip9Ei7ym67VZRF8Sg0BWRCwA6h9Ei4L3BUgWwNG0it.)

ii [Hauser SL, Bar-Or A, Cohen JA, Comi G, Correale J, Coyle PK, Cross AH, de Seze J, Leppert D, Montalban X, Selmaj K, Wiendl H, Kerloeguen C, Willi R, Li B, Kakarieka A, Tomic D, Goodyear A, Pingili R, Haring DA, Ramanathan K, Merschhemke M, Kappos L; ASCLEPIOS I and ASCLEPIOS II Trial Groups. Ofatumumab versus Teriflunomide in Multiple Sclerosis. N Engl J Med. 2020 Aug 6;383(6):546-557. doi: 10.1056/NEJMoa1917246.](https://clinicaltrials.gov/ct2/bye/rQoPWwoRrXS9-i-wudNgpQDxudhWudNzlXNiZip9Ei7ym67VZRFn-gCwLR0RA6h9Ei4L3BUgWwNG0it.)

iii 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.