Insurance Co Name

Insurance Co Address

September 30, 2024

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 Ocrevus Zunovo™(ocrelizumab & hyaluronidase-ocsq) 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.

Ocrevus Zunovo is medically necessary for my patient because insert rationale here. This is supported by the American Academy of Neurology Practice Guideline recommendation, which can be found at this web address: (<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. as well as a spinal tap where OCBs were detected in the CSF.

OCREVUS ZUNOVO 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, ocrelizumab 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 or primary progressive forms of multiple sclerosis in 2024.

Ocrevus Zunovo has the same mechanism of action as Ocrevus IV, but is available as an Healthcare Provider (HCP)-administered subcutaneous (SC) injection rather than intravenous (IV) infusion.

**If patient has primary progressive disease, include the following paragraph:**

Ocrevus and Ocrevus Zunovo are the only disease modifying therapies specifically indicated to treat primary progressive MS. The ORATORIO study, involving 732 people with primary progressive MS, compared Ocrevus to inactive placebo. In this study Ocrevus significantly reduced the risk of progression of clinical disability by 25% and reduced the time required to walk 25 feet by 29% compared with placebo. Ocrevus also decreased the number of brain lesions on MRI by 3.4% vs. 7.4% increase with placebo and reduced brain volume loss by 17.5% compared with placebo.i OCARINA II, a Phase III, randomized, open-label, controlled trial demonstrated that blood levels of ocrelizumab were similar when administered via subcutaneous (SC) vs intravenous (IV) routes.

**If patient has a relapsing form of MS, include the following paragraph:**

In the OPERA I and OPERA II studies involving people with relapsing MS, which compared Ocrevus to interferon beta-1a (Rebif, ® EMD Serono and Pfizer), Ocrevus significantly reduced the annualized relapse rate by up to 47% compared with Rebif over two years in a total of 1,656 people with relapsing MS. In addition, Ocrevus significantly delayed confirmed progression of disability on the estimated disability status scale (EDSS) by 40% compared with Rebif. Ocrevus also significantly reduced the number of enhancing lesions observed on MRI by up to 95% compared with Rebif. ii OCARINA II, a Phase III, randomized, open-label, controlled trial demonstrated that blood levels of ocrelizumab were similar when administered via subcutaneous (SC) vs intravenous (IV) routes.v

[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. iii

Additionally, a phase IIIb studyiv of patients switched to Ocrevus with a suboptimal response to prior disease modifying therapies revealed that a substantial portion (48%) of patients achieved having no evidence of disease activity (NEDA) over 96 weeks. Patients had previously failed disease modifying drugs including glatiramer acetate, fingolimod, teriflunomide, dimethyl fumarate and interferon beta 1a or interferon beta 1b due to either breakthrough MRI activity or clinical relapse.

Ocrevus Zunovo 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 Montalban X and The ORATORIO Clinical Investigators, *Ocrelizumab v., Placebo in Primary Progressive MS,* N Engl J Med 2017; 376:209-220, January 19, 2017.

ii Hauser SL and The OPERA I and OPERA II Clinical Investigators, *Ocrelizumab* *vs. Interferon Alpha 1-a in Relapsing* *Multiple Sclerosis*, N Engl J Med 2017; 376:221-234 January 19, 2017.

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.

iv Weinstock-Guttman B, Bermel R, Cutter G, Freedman MS, Leist TP, Ma X, Kile D, Musch B, Reder AT, Wolinsky JS. Ocrelizumab treatment for relapsing-remitting multiple sclerosis after a suboptimal response to previous disease-modifying therapy: A nonrandomized controlled trial. Mult Scler. 2022 Apr;28(5):790-800.

v Newsome, Scott, et al. OCARINA II, Phase III Study: Results of Subcutaneous Ocrelizumab Administration in Patients with Multiple Sclerosis (S31.006). Neurology. 2024 Apr 9; 102(17 Supplement 1).