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 Lemtrada® (alemtuzumab) 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.

Lemtrada 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.

Lemtrada is a humanized monoclonal antibody presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes, and macrophages. Following cell surface binding to T and B lymphocytes, alemtuzumab results in antibody-dependent cellular cytolysis and complement-mediated lysis.

The FDA approved Lemtrada based on the results of two large, phase III clinical trials that confirmed its ability to significantly reduce relapse rates over two years over standard subcutaneous dosing of Rebif® (interferon beta-1a, EMD Serono Inc. and Pfizer).

In the CARE-MS I trial 563 patients with early, active relapsing-remitting MS, who had never received disease-modifying therapy to treat their MS were randomly assigned to receive Lemtrada or Rebif. After two years the relapse rate for those on Lemtrada was reduced by 55% compared to those on Rebif. After two years 78% of those on Lemtrada remained relapse-free, which was significantly more than the 59% who remained relapse-free on Rebif. 1

In the CARE-MS II trial 628 patients with relapsing-remitting MS who had at least one relapse while on interferon beta or glatiramer acetate were randomly assigned to receive Lemtrada or Rebif. After two years, the annual relapse rate for those on Lemtrada was 0.26 compared to 0.52 for those on Rebif, representing a 49% reduction in relapses. Fewer people on Lemtrada had an increase (worsening) in their EDSS score compared to those on Rebif (13% for Lemtrada vs. 21% for Rebif) – a 42% difference that was statistically significant. After two years, 65% of those on Lemtrada remained relapse-free compared to 47% on Rebif, which was also statistically significant.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

Lemtrada 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 Cohen JA, Coles AJ, Arnold DL, Confavreux C, Fox EJ, Hartung HP, Havrdova E, Selmaj KW, Weiner HL, Fisher E, Brinar VV, Giovannoni G, Stojanovic M, Ertik BI, Lake SL, Margolin DH, Panzara MA, Compston DA; CARE-MS I investigators. Alemtuzumab versus interferon beta 1a as first-line treatment for patients with relapsing-remitting multiple sclerosis: a randomized controlled phase 3 trial. *Lancet.* 2012 Nov 24; 380(9856):1819-28.

2 Coles AJ, Twyman CL, Arnold DL, Cohen JA, Confavreux C, Fox EJ, Hartung HP, Havrdova E, Selmaj KW, Weiner HL, Miller T, Fisher E, Sandbrink R, Lake SL,Margolin DH, Oyuela P, Panzara MA, Compston DA; CARE-MS II investigators. Alemtuzumab for patients with relapsing multiple sclerosis after disease-modifying therapy: a randomized controlled phase 3 trial. *Lancet*. 2012 Nov 24; 380(9856):1829-39.

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-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.