Insurance Co Name

Insurance Co Address

December 4, 2019

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 Vumerity™ (diroximel fumarate) for my patient, enter patient namefor the management of choose his/her 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.

Vumerity is medically necessary for my patient because insert rationale here.

Vumerity is similar to dimethyl fumarate (Tecfidera® Biogen) but has a distinct chemical structure and has been shown to have fewer reported gastrointestinal side effects than Tecfidera. Vumerity was FDA approved in 2019 for use in relapsing forms which includes clinically isolated syndrome, relapsing-remitting MS and active secondary-progressive MS.

Vumerity and Tecfidera convert in the body to the same active metabolite, monomethyl fumarate, and therefore, the FDA approval is based upon the Phase 3 clinical trial data for Tecfidera. Tecfidera demonstrated safety and efficacy in relapsing multiple sclerosis in two phase III clinical trials. In the DEFINE trial, Tecfidera produced a 49% reduction in relapses over 2 years and had a similar significant reduction of disease activity on brain MRI. Tecfidera also demonstrated a 38% reduction in the risk of confirmed progression of disability as measured by the Expanded Disability Status Scale (EDSS).1 In the CONFIRM trial, Tecfidera produced a significant 44% reduction in the annualized relapse rate compared with the placebo group. An active reference group taking glatiramer acetate (Copaxone®) was included in this study, which reduced the annualized relapse rate by 29% compared to placebo. Participants taking Tecfidera in this trial also had a similar significant reduction of disease activity on MRI.2

An additional tolerability study of Vumerity indicated improved GI tolerability compared to Tecfidera3.

Please refer to the consensus paper by the [Multiple Sclerosis Coalition entitled The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence](http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color) for evidence in support of early and ongoing access to the full range of therapy options for patients with MS.4

[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.5

Vumerity 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.

 Gold R, Kappos L, Arnold DL, DEFINE Study Investigators. “Placebo-controlled phase 3 study of oral BG-12 for relapsing multiple sclerosis”. [*N Engl J Med.* 2012 Sep 20;367(12):1098-107](http://www.ncbi.nlm.nih.gov/pubmed/22992073).

2 Fox RJ, Miller DH, Phillips JT, Hutchinson M, Havrdova E, Kita M, Yang M, Raghupathi K, Novas M, Sweetser MT, Viglietta V, Dawson KT; CONFIRM Study Investigators. Placebo-controlled phase 3 study of oral BG-12 or glatiramer in multiple sclerosis. [*N Engl J Med*. 2012 Sep 20;367(12):1087-97](http://www.ncbi.nlm.nih.gov/pubmed/22992072).

3 Palte MJ, Wehr A, Tawa M, Perkin K, Leigh-Pemberton R, Hanna J, Miller C, Penner N. Improving the Gastrointestinal Tolerability of Fumaric Acid Esters: Early Findings on Gastrointestinal Events with Diroximel Fumarate in Patients with Relapsing-Remitting Multiple Sclerosis from the Phase 3, Open-Label EVOLVE-MS-1 Study. Adv Ther. 2019 Nov;36(11):3154-3165.

4 Costello K and Kalb R. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. Consensus Paper by the Multiple Sclerosis Coalition. 2018.

5 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-modifyingtherapies 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.