Insurance Co Name

Insurance Co Address

Date

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 Bafiertam® (monomethyl fumarate) 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.

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

Bafiertam is bioequivalent to dimethyl fumarate (Tecfidera® Biogen) and similar to diroximel fumarate (Vumerity® Biogen) but has a distinct chemical structure and a GI tolerability study in healthy subjects showed a trend towards fewer reported GI side effects than Tecfidera1, and unlike Vumerity has no label restrictions with respect to food and alcohol consumption. Whereas Vumerity is not recommended in patients with moderate or severe renal impairment, Bafiertam has no such restriction. The lack of such restrictions may improve patient adherence with Bafiertam treatment. Bafiertam was FDA approved in 2020 for use in relapsing forms of MS, 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 of Bafiertam 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).2 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.3

[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.4

Bafiertam 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 Wynn D,Lategan TW, Sprague TN, [Rousseau](https://www.sciencedirect.com/science/article/pii/S2211034820304119#!) FS, [Fox EJ](https://www.sciencedirect.com/science/article/pii/S2211034820304119#!). Monomethyl fumarate has better gastrointestinal tolerability profile compared with dimethyl fumarate. [Multiple Sclerosis and Related Disorders](https://www.sciencedirect.com/science/journal/22110348). [Volume 45](https://www.sciencedirect.com/science/journal/22110348/45/supp/C), October 2020, 102335. <https://doi.org/10.1016/j.msard.2020.102335>

2 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).

3 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).

4 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.