Insurance Co Name

Insurance Co Address

November 14, 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 reconsideration of denial of coverage of insert DMT name 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 was prescribed insert DMT name to treat choose his/her highly active form of MS, which was diagnosed in enter year . Based on the data presented in this letter, insert DMT name is medically necessary and the most appropriate treatment for my patient with justifications provided herein.

Multiple sclerosis is an unpredictable immune-mediated disease of the central nervous system (CNS) associated with progressive axonal demyelination and neurodegeneration. Without appropriate treatment in the initial inflammatory phase, the disease can rapidly progress causing permanent disability. Highly active and/or aggressive MS is characterized by features that predict a patient may have a more aggressive course with increased risk of disability over time. These poor prognostic features include one or more of the following: frequent relapses, severe relapses (e.g. resulting in functional limitations), incomplete relapse recovery, high burden of lesions seen on MRI and/or continued lesion accumulation despite treatment, high burden of enhancing lesions, lesion location (brainstem and spinal cord involvement), and/or rapid accumulation of disability [1-5]. Demographic risk factors have also been identified, to include male sex, age >40 at disease onset, and non-white race [5]. The Multiple Sclerosis Coalition, consisting of a panel of MS experts, has noted substantial evidence of superior outcomes when aggressive treatment is started in the initial stages of disease [6]. Identifying individuals at risk for highly active forms of MS and providing appropriate treatment options early in the disease course is **critical** in reducing disease progression and permanent disability.

Enter patient name has the following risk factors for highly active and/or aggressive disease as defined in the paragraph above:

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Early MS disease activity drives long-term disability. In light of this knowledge, there is growing evidence to support more favorable outcomes when utilizing high-efficacy drugs in the treatment of highly active MS as opposed to conventional step-therapy algorithms [4, 7-9]. According to the 2018 American Academy of Neurology [AAN] *Practice guideline: Disease-modifying therapies for adults with multiple sclerosis*, initiating treatment with a highly effective disease modifying therapy in individuals presenting with poor prognostic factors associated with highly active MS is best standard practice. The consensus paper by the Multiple Sclerosis Coalition, *The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence,* also supports early and ongoing access to the full range of therapy options for patients with MS.

High efficacy drugs include natalizumab, alemtuzumab, ocrelizumab, and cladribine [6, 10]. These medications should be considered for individuals with highly active MS, to include those who are both newly diagnosed and those who have experienced breakthrough activity on another disease-modifying therapy [6, 10].

Insert DMT name is medically necessary for my patient. Based on research data, clinical expertise, and disease state, insert DMT name is the most appropriate treatment option for this patient to reduce disability, effectively decrease relapses, and delay disability progression. Delaying or failing to approve the most appropriate treatment further compromises patient care and may result in serious adverse effects, including permanent disability. I respectfully request that you 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. Fisniku, L.K., et al., *Disability and T2 MRI lesions: a 20-year follow-up of patients with relapse onset of multiple sclerosis.* Brain, 2008. 131(Pt 3): p. 808-17.

2. Scalfari, A., et al., *The natural history of multiple sclerosis: a geographically based study 10: relapses and long-term disability.* Brain, 2010. 133(Pt 7): p. 1914-29.

3. Menon, S., et al., *Characterising aggressive multiple sclerosis.* J Neurol Neurosurg Psychiatry, 2013. 84(11): p. 1192-8.

4. Kaunzner, U.W., et al., *A study of patients with aggressive multiple sclerosis at disease onset.* Neuropsychiatr Dis Treat, 2016. 12: p. 1907-12.

5. Diaz, C., L.A. Zarco, and D.M. Rivera, *Highly active multiple sclerosis: An update.* Mult Scler Relat Disord, 2019. 30: p. 215-224.

6. Costello, K., et al., *Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis: principles and current evidence*. 2019.

7. Rush, C.A., H.J. MacLean, and M.S. Freedman, *Aggressive multiple sclerosis: proposed definition and treatment algorithm.* Nat Rev Neurol, 2015. 11(7): p. 379-89.

8. Harding, K., et al., *Clinical Outcomes of Escalation vs Early Intensive Disease-Modifying Therapy in Patients With Multiple Sclerosis.* JAMA Neurol, 2019. 76(5): p. 536-541.

9. Havrdova, E., et al., *Effect of natalizumab on clinical and radiological disease activity in multiple sclerosis: a retrospective analysis of the Natalizumab Safety and Efficacy in Relapsing-Remitting Multiple Sclerosis (AFFIRM) study.* Lancet Neurol, 2009. 8(3): p. 254-60.

10. Rae-Grant, A., et al., *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. 90(17): p. 777-788.