[Physician Letterhead]

[Date]

[Name of Pharmacy/Payer Contact]

[Name of Health Insurance Company]

[Address]

[City, State, ZIP Code]

Re: Coverage for Hydroxocobalamin

Patient: [Patient Name]

Date of Birth: [Date]

Diagnosis: [Diagnosis], [ICD-10-CM]

Group/Policy Number: [Number]

Policyholder: [Policyholder Name]

Dear [Pharmacy Director/Payer Contact Name]:

I am writing on behalf of my patient, [Patient Name], to document the medical necessity to treat their [Diagnosis] with hydroxocobalamin.

This letter serves to document my patient’s medical history and diagnosis and to summarize my treatment rationale. Please refer to the [List any Enclosures] enclosed with this letter.

**Summary of Patient’s Medical History and Diagnosis**

[Patient Name] is [Age] years old and was initially diagnosed with [Diagnosis] [ICD-10-CM] on [Date]. [Patient Name] has been in my care since [Date]. [Provide a discussion of the patient’s clinical history, current symptoms and condition, any potential contraindications, and any relevant laboratory test results, highlighting the factors leading you to recommend use of the product]

**Rationale for Treatment**

Hydroxocobalamin is used to lower total homocysteine levels for patients with inherited metabolic disorders including homocystinuria, and cobalamin defects C, D, E, F, G, J, K and X. Hydroxocobalamin acts as a cofactor for the remethylation process, which provides an essential function in converting homocysteine into methionine. This is not the same as a nutritional B12 deficiency.

Heumer, *et al* in a published article titled, “Guidelines for diagnosis and management of the cobalamin-related remethylation disorders cblC, cblD, cblE, cblF, cblG, cblJ and MTHFR deficiency” stated, “We strongly recommend to initiate treatment with parenteral hydroxocobalamin without delay in any suspected remethylation disorder; it significantly improves survival and incidence of severe complications.”1

In addition, Sloan, *et al,* states, “Early institution of injectable hydroxocobalamin improves survival and may reduce but not completely prevent primary manifestations. To prevent metabolic decompensations, patients are advised to avoid situations that result in catabolism, such as prolonged fasting and dehydration, and always remain on a weight-appropriate dose of hydroxocobalamin.”2

The use of oral hydroxocobalamin (OHCbl) and cyanocobalamin (CNCbl) has been reviewed by Nuria Carrillo-Carrasco and Charles P Venditti stating, “The review of published case reports discourages the use of CNCbl and oral OHCbl alone in the treatment of cblC, as they were associated consistently with a poor outcome in the cases reviewed. Parenteral OHCbl remains the treatment of choice, and its use has likely decreased the infantile mortality rate.” 3

Carillo-Carrasco, *et* al also states, “The use of higher doses of parenteral OHCbl has been effective at reducing metabolites.” 3

While hydroxocobalamin is available over the counter at a concentration of 1000 mcg/ml, this concentration cannot meet the needs of [Patient Name] and therefore, needs to be compounded at a higher concentration of [Concentration].

In summary, hydroxocobalamin is medically necessary to treat [Patient Name’s] [Diagnosis], and I ask you to please consider coverage of hydroxocobalamin on [Patient Name’s] behalf. Please refer to the enclosed supporting documents for further details, and do not hesitate to call me on [Phone Number] if you have any questions or if you require additional information.

Thank you for your attention to this matter.

Sincerely,

[Prescribing Physician Name and Credentials] [NPI Number]

Enclosures: [List any Enclosures, such as: Prescribing Information, Medication Guide, and Clinical Notes]

1Huemer, M., Diodato, D., Schwahn, B. et al. Guidelines for diagnosis and management of the cobalamin-related remethylation disorders cblC, cblD, cblE, cblF, cblG, cblJ and MTHFR deficiency. J Inherit Metab Dis 40, 21–48 (2017). https://doi.org/10.1007/s10545-016-9991-4

2Sloan JL, Carrillo N, Adams D, et al. Disorders of Intracellular Cobalamin Metabolism. 2008 Feb 25 [Updated 2021 Dec 16]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1328/>

3 Carrillo-Carrasco N, Chandler RJ, Venditti CP. Combined methylmalonic acidemia and homocystinuria, cblC type. I. Clinical presentations, diagnosis and management. J Inherit Metab Dis. 2012 Jan;35(1):91-102. doi: 10.1007/s10545-011-9364-y. Epub 2011 Jul 12. PMID: 21748409; PMCID: PMC4219318.