Insurance Company

**RE: PATIENT**

**DOB:**

**ID#**

**Pat Acct #**

Dear Sir, or Madam:

I am writing this letter on behalf of my patient, PATIENT NAME, to request that you reconsider your decision to deny payment for the vedolizumab trough test that was performed on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  This test measures the level of vedolizumab and checks for the presence of anti-vedolizumab antibodies.

INSERT PATIENT’s CLNICAL SITUATION AND REASON FOR ODERING TEST HERE

Despite the efficacy of our currently available biologic agents, up to 30% of patients do not respond to their prescribed treatment (primary non-response), and another 50% may ultimately lose response to their treatment over time (secondary loss of response).1,2 A significant proportion of these patients may be found to have suboptimal drug levels either due to inadequate dosing or development of anti-drug antibodies, the latter which result in increased drug clearance.3 The practice of therapeutic drug monitoring (TDM), through which drug concentrations and the presence of anti-drug antibodies are measured, is a necessary tool used to understand *why* an individual patient is not responding or has lost response to a therapy. The results of such testing can facilitate decision-making, specifically as to whether a specific biologic can be further dose-optimized to improve clinical response, or if rather a treatment change to a different biologic would be indicated. This helps to improve clinical outcomes and prevent unnecessary biologic switches. An expert consensus statement was published in 2021 following a comprehensive literature review, supporting the use of TDM for all biologics in the setting of primary non-response and secondary loss of response.4

There is ample data to support the use of TDM with vedolizumab therapy in the setting of primary nonresponse or loss-of-response to treatment.5-14 Vedolizumab trough concentrations 12-15 mcg/mL have been associated with clinical or endoscopic remission.6,8,14 In clinical trials, approximately 4% of vedolizumab treated patients developed anti-drug antibodies, which may impact drug clearance and result in lower trough concentrations with reduced efficacy of the drug itself. The referenced papers show that therapeutic drug monitoring of biologics is rapidly becoming a standard of care in the field of inflammatory bowel disease.

In this clinical setting where PATIENT has NOT RESPONDED/LOST RESPONSE to vedolizumab, it was entirely appropriate to pursue TDM to determine whether the dose of vedolizumab could be optimized or if we would need to consider switching to a different mechanism of action altogether.  The referenced papers show that TDM with biologics is rapidly becoming a standard of care in the field of inflammatory bowel disease.

For these reasons, we ask that you please reconsider your decision to deny payment for the vedolizumab trough test. Feel free to contact me if you require additional information.

Sincerely,

DOCTOR

**CLINICAL REFERENCEs**

1. Vande Casteele N, Herfarth H, Katz J, et al. American Gastroenterological Association institute technical review on the role of therapeutic drug monitoring in the management of inflammatory bowel Diseases. Gastroenterology 2017;153:835–57.

1. Sparrow MP, Papamichael K, Ward MG, et al. Therapeutic drug monitoring of biologics during induction to prevent primary non-response. J Crohns Colitis 2020;14:542–56.
2. Vermeire S, Dreesen E, Papamichael K, et al. How, when, and for whom should we perform therapeutic drug monitoring? Clin Gastroenterol Hepatol 2020;18:1291–9.
3. Cheifetz AS, Abreu MR, Afif W, et al. A Comprehensive Literature Review and Expert Consensus Statement on Therapeutic Drug Monitoring of Biologics in Inflammatory Bowel Disease. Am J Gastroenterol. 2021 Oct;116(10):2014-25.
4. Williet N, Boschetti G, Fovet M, et al: Association between low trough levels of vedolizumab during induction therapy for inflammatory bowel diseases and need for additional doses within 6 months. Clin Gastroenterol Hepatol. 2017 Nov;15(11):1750-1757.e3
5. Dreesen E, Verstockt B, Bian S, et al: Evidence to support monitoring of vedolizumab trough concentrations in patients with inflammatory bowel diseases. Clin Gastroenterol Hepatol 2018 Dec;16(12):1937-1946 e8
6. Ungar B, Kopylov U, Yavzori M, et al: Association of vedolizumab level, anti-drug antibodies, and alpha4beta7 occupancy with response in patients with inflammatory bowel diseases. Clin Gastroenterol Hepatol. 2018 May;16(5):697-705.e7
7. Ward MG, Sparrow MP, Roblin X: Therapeutic drug monitoring of vedolizumab in inflammatory bowel disease: Current data and future directions. Therap Adv Gastroenterol. 2018 May 8;11:1756284818772786
8. Pouillon L, Rousseau H, Busby-Venner H, et al: Vedolizumab trough levels and histological healing during maintenance therapy in ulcerative colitis. J Crohns Colitis. 2019 Aug 14;13(8):970-975
9. Pouillon L, Vermeire S, Bossuyt P: Vedolizumab trough level monitoring in inflammatory bowel disease: A state-of-the-art overview. BMC Med. 2019 May 8;17(1):89
10. Singh S, Dulai PS, Vande Casteele N, et al: Systematic review with meta-analysis: Association between vedolizumab trough concentration and clinical outcomes in patients with inflammatory bowel diseases. Aliment Pharmacol Ther. 2019 Oct;50(8):848-857
11. Ungaro RC, Yarur A, Jossen J, et al: Higher trough vedolizumab concentrations during maintenance therapy are associated with corticosteroid-free remission in inflammatory bowel disease. J Crohns Colitis. 2019 Aug 14;13(8):963-969
12. Yarur AJ, Bruss A, Naik S, et al: Vedolizumab concentrations are associated with long-term endoscopic remission in patients with inflammatory bowel diseases. Dig Dis Sci. 2019 Jun;64(6):1651-1659
13. Al-Bawardy B, Ramos GP, Willrich MAV, et al: Vedolizumab drug level correlation with clinical remission, biomarker normalization, and mucosal healing in inflammatory bowel disease. Inflamm Bowel Dis. 2019 Feb 21;25(3):580-586