Insurance Company

**RE: PATIENT**

**DOB:**

**ID#**

To whom it may concern,

I am writing this letter on behalf of PATIENT NAME, whom I follow at **LOCATION** for the care of Crohn’s disease/ulcerative colitis to request reconsideration of the denial to cover the serum infliximab level that was performed on DATE.  This test measures the level of infliximab and checks for the presence of anti-drug antibodies.

INSERT PATIENT’s CLNICAL SITUATION AND REASON FOR ORDERING 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 have suboptimal drug levels either due to inadequate dosing or development of anti-drug antibodies, the latter which result in increased drug clearance.3 Thus, therapeutic drug monitoring (TDM), which measures drug concentrations and the presence of anti-drug antibodies, is a necessary tool to understand *why* an individual patient is not responding or has lost response to a therapy. The results of such testing facilitates decision-making, specifically as to whether a specific biologic can be further dose optimized to improve clinical response, or if a treatment change to a different biologic would be the next best step to optimize patient outcomes. 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

Patient has lost response to infliximab, meaning that obtaining infliximab drug levels through TDM to help guide further therapy is necessary. These results help determine if he/she needs increased dose/frequency of infliximab or a change in therapy before an adverse event occurs from suboptimally controlled disease or immunogenicity. The infliximab level helps us efficiently treat this patient with the correct medication, at the right dose, with minimal wasted resources.

There is ample clinical data to support the use of TDM for infliximab. References including the AGA guidelines on therapeutic drug monitoring, which support TDM in setting of active IBD for those on tumor necrosis factor inhibitors like infliximab are included below.5-9 The use of TDM is rapidly becoming standard of care in IBD management, as it is otherwise impossible to confidently know how to manage primary non-response or secondary loss of response in these patients.

Feel free to contact me if you require additional information. I look forward to hearing from you and reconsideration of coverage for this test.

Kind regards,

Dr.

Contact Info

**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.
2. 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.
3. 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.
4. 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.
5. Feuerstein JD, Nguyen GC, Kupfer SS, et al. American Gastroenterological Association Institute Guideline on Therapeutic Drug Monitoring in Inflammatory Bowel Disease. Gastroenterology. 2017;153(3):827-34.
6. Ordas I, Feagan BG, Sandborn WJ: Therapeutic drug monitoring of tumor necrosis factor antagonists in inflammatory bowel disease. Clin Gastroenterol Hepatol. 2012 Oct;10(10):1079-1087; quiz e85-86
7. Papamichael K, Cheifetz AS, Melmed GY, et al. Appropriate Therapeutic Drug Monitoring of Biologic Agents for Patients With Inflammatory Bowel Diseases. Clin Gastroenterol Hepatol. 2019;17:1655-68.
8. Papamichael K, Vande Casteele N, Jeyarajah J, et al. Higher postinduction infliximab concentrations are associated with improved clinical outcomes in fistulizing Crohn’s disease: an ACCENT-ii post hoc analysis. Am J Gastroenterol. 2020;00:1-8.
9. Yarur AJ, Kanagala V, Stein DJ, et al. Higher infliximab trough levels are associated with perianal fistula healing in patients with Crohn’s disease. Aliment Pharmacol Ther. 2017;45(7):933-940.