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 adalimumab trough test that was performed on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  This test measures the level of adalimumab 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

In this clinical setting, an adalimumab level was obtained to determine how to optimize this patient’s therapy and care. It is not ideal to manage the loss of response to adalimumab without checking adalimumab trough levels and antibodies, and use of this test can help reduce improper utilization of IBD treatments. There is ample clinical data to support the use of TDM for adalimumab. 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 adalimumab are listed below for your review.5-11

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

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.
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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.
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7. Restellini S, Chao CY, Lakatos PL, et al: Therapeutic drug monitoring guides the management of Crohn's patients with secondary loss of response to adalimumab. Inflamm Bowel Dis. 2018 Jun 8;24(7):1531-1538
8. 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.
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11. Kato M, Sugimoto K, Ikeya K, et al: Therapeutic monitoring of adalimumab at non-trough levels in patients with inflammatory bowel disease. PLoS One. 2021 Jul 9;16(7):e0254548