SAMPLE APPEAL LETTER – ADALIMUMAB DOSE ESCALATION

Insurance Company

# RE: PATIENT

**DOB:**

**ID #**

**Pat Acct #**

DATE

Dear Sir, or Madam:

I am writing on behalf of my patient, Mr./Ms. Doe, to request prior authorization for increased dosing of adalimumab from 40mg every two weeks to 40mg weekly.

Mr./Ms. Doe has a history of [IBD Phenotype and prior surgeries/complications (e.g., fistulas, abscess, strictures)] and has previously failed treatment with [Previous medication failures and/or intolerances]. Mr./Ms. Doe was started on adalimumab [Month/Year of induction] and has done well on adalimumab 40mg every 2 weeks maintenance therapy until recently.

Unfortunately, since [Date of flare symptoms] Mr./Ms. Doe has developed increasing symptoms of active disease [can also add pertinent colonoscopy, CRP, calprotectin, or adalimumab level data here] despite ongoing treatment with adalimumab 40mg every 2 weeks. Given his/her previous medication failures, initial clinical response to adalimumab therapy, and ongoing active inflammation, I am requesting approval for an increase to adalimumab 40mg once weekly dosing.

The efficacy of adalimumab for the induction/maintenance of remission in Crohn’s and ulcerative colitis was demonstrated in the CLASSIC (Crohn’s) and ULTRA (UC) clinical trials. In these pivotal trials, 30% (CLASSIC II) and 16% (ULTRA 2) of patients required dose escalation to 40mg once weekly, due to an inadequate clinical response.1,2 In a subsequent multicenter cohort study by Baert et al, 34% of Crohn’s patients on adalimumab 40mg every 2 weeks required dose escalation to 40mg once weekly, due to loss of clinical response, with 67% of these patients maintaining a long-term clinical response.3 Similarly, in a multicenter cohort study by Taxonera et al, among ulcerative colitis patients experiencing loss of response on adalimumab 40mg every 2 weeks, 47% achieved a short-term clinical response, and 34% maintained a long-term clinical response after dose escalation to adalimumab 40mg once weekly.4

These data confirm that the need for adalimumab dose escalation is a common, and that this strategy is successful in re-capturing a clinical response for a significant number of patients with Crohn’s or ulcerative colitis. It is certainly the most conservative course of action for this patient, as we know that he/she has responded to the mechanism of action of adalimumab. In addition, changing Mr./Ms. Doe to an alternative medication prior to a trial of dose escalation could put the patient at risk to develop anti-drug antibodies and may limit future use of adalimumab. Given our limited treatment options for IBD, it is in the best interest of the patient to optimize the current biologic before switching to a different medication.

Based on the data presented in this letter and my professional experience, I am advocating that adalimumab 40mg once weekly be a covered benefit for Mr./Ms. Doe. I appreciate your consideration in this matter. As my patient is suffering with symptoms at this time that put him/her at risk to develop serious complications from his/her disease, I hope that you can expedite this request so that he/she can be started on therapy as soon as possible. Please feel free to contact my office if any additional information will help clarify this request.

Sincerely,

Dr.

Contact info

References:

1. Sandborn et al. Adalimumab for maintenance treatment of Crohn’s disease: results of the CLASSIC II trial. Gut 2007; 56:1232–1239

2. Sandborn et al. Adalimumab induces and maintains clinical remission in patients with moderate-to-severe ulcerative colitis. Gastroenterology. 2012;142(2):257-65

3. Baert et al. Incidence and Predictors of Success of Adalimumab Dose Escalation and De-escalation in Ulcerative Colitis: a Real-World Belgian Cohort Study. J Crohn’s Colitis. 2013;7(2):154-60

4. Taxonera et al. Adalimumab Maintenance Treatment in Ulcerative Colitis: Outcomes by Prior Anti-TNF Use and Efficacy of Dose Escalation. Dig Dis Sci. 2017;62(2):481-490