SAMPLE APPEAL LETTER – USTEKINUMAB 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 ustekinumab from 90mg every eight weeks to every 4 week dosing.

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 ustekinumab [Month/Year of induction] and has done well on standard dosing 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 ustekinumab level data here] despite ongoing treatment with ustekinumab 90mg every 8 weeks. Given his/her previous medication failures, initial clinical response to ustekinumab therapy with ongoing active inflammation, I am requesting approval for an increase to ustekinumab 90 mg SQ every 4 weeks.

Multiple studies have demonstrated that a substantial group of patients lose response to ustekinumab 90 mg q8 week dosing. In a recent study of 110 patients with Crohn’s disease, ustekinumab interval shortening to every 4 weeks resulted in a **significant improvement in symptoms and C-reactive protein**.1 In one such cohort of patients who achieved corticosteroid-free remission after induction, dose escalation or combined reinduction and dose escalation to ustekinumab 90 mg SQ q4-6 weeks was required in 24% of patients. Over 50% of these patients recaptured response2. In another study, initial clinical response to ustekinumab was achieved in 74% of Crohn’s disease patients, however, **dose escalation was required in 48% of patients and was successful in recapturing response for 61% of patients**3**.** Yet another study of usteknimuab in Crohn’s disease in a Canadian tertiary care center experience reported a 56% response rate to ustekinumab4. However, **42% of initial responders required dose escalation of ustekinumab**.

These studies demonstrate among Crohn’s disease patients that, the requirement for dose escalation is common and is a successful strategy to capture response in the majority of patients. We know from our vast experience with other biologics that these medications are metabolized rapidly in patients with highly active disease and therefore dose escalation is quite commonly required and, in fact, expected in severe disease. Dose escalation of ustekinumab 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 ustekinumab. In addition, changing this patient 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 ustekinumab.

Based on the data presented in this letter and my professional experience, I am advocating that ustekinumab 90mg every 4 weeks 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. Ollech JE et al, Effectiveness of Ustekinumab Dose Escalation in Patients With Crohn's Disease. Clin Gastroenterol Hepatol. 2020 Feb 26. [Epub ahead of print]
2. Ma et al, Long-term Maintenance o Clinical, Endoscopic, and Radiologic response to ustekinumab in Moderate to Severe Crohn’s disease: Real world experience from a Multicenter Cohort Study. Inflamm Bowel Disease. 2017;23:833-839.
3. Kopylov et al, Subcutaneous ustekinumab for the treatment of anti-TNF resistant Crohn's disease--the McGill experience, J Crohn’s Colitis. 2014;8:1516-22.
4. Greenup et al, Ustekinumab use in Crohn's disease: a Canadian tertiary care centre experience, Scand J Gastroenterol. 2017;52:1354-59.