SAMPLE APPEAL LETTER – VEDOLIZUMAB 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 vedolizumab from 300 mg every eight weeks to every 4 weeks.

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 vedolizumab [Month/Year of induction] and has done well on a vedolizumab at 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 vedolizumab level data here] despite ongoing treatment with vedolizumab 300mg every 8 weeks. Given his/her previous medication failures, initial clinical response to vedolizumab therapy, and ongoing active inflammation, I am requesting approval for an increase to vedolizumab 300 mg q4 weeks.

The GEMINI long-term safety (LTS) study investigated the effects of increased dosing frequency to every 4 weeks for 57 patients who received vedolizumab every 8 weeks during maintenance phase of GEMINI II but withdrew early because of sustained non-response, disease worsening or need for rescue medication1. The shortened dosing interval was effective at recapturing response in 47% and remission in 32% of patients at 52 weeks. Shortened dosing interval has also proven to be efficacious in inducing clinical response and remission in patients who were originally non-responsive to an every 8 week dosing interval.  The GEMINI series has demonstrated the safety of maintenance vedolizumab at both dosing intervals of every 8 and 4 weeks in moderate to severe ulcerative colitis and Crohn’s disease patients. In addition, a recent meta-analysis of four studies showed that vedolizumab dose intensification restored response in 54% of patients with inflammatory bowel disease who had secondary non-response to the drug2.

These data confirm that the need for vedolizumab dose escalation is common, and that this strategy is successful in re-capturing a clinical response for a significant number of patients with Crohn’s disease 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 vedolizumab. Switching 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 vedolizumab.

Based on the data presented in this letter and my professional experience, I am advocating that vedolizumab 300 mg q4 weeks be a covered benefit for Mr./Ms. Doe. I appreciate your consideration in this matter. As my patient is suffering with active symptoms at this time that put him/her at risk to develop disease-related complications including need for corticosteroids, hospitalization and surgery, 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. Vermeire S et al, Long-term Efficacy of Vedolizumab for Crohn’s Disease, [J Crohns Colitis.](https://www.ncbi.nlm.nih.gov/pubmed/27683798) 2017 Apr 1;11(4):412-424.
2. [Peyrin-Biroulet L](https://www.ncbi.nlm.nih.gov/pubmed/?term=Peyrin-Biroulet%20L%5BAuthor%5D&cauthor=true&cauthor_uid=29935327) et al, Loss of Response to Vedolizumab and Ability of Dose Intensification to Restore Response in Patients With Crohn's Disease or Ulcerative Colitis: A Systematic Review and Meta-analysis. [Clin Gastroenterol Hepatol.](https://www.ncbi.nlm.nih.gov/pubmed/29935327) 2019 Apr;17(5):838-846.e2