Insurance Company

**RE: PATIENT**

**DOB:**

**ID#**

**Pat Acct #**

**Date**

Dear Sir/Madam:

I am writing on behalf of Mr./Ms Doe to request prior authorization to increase the current infliximab dose, and to provide you with detailed medical information to support the change. I am requesting to increase the current dose from 5mg (every 8 weeks) to 10mg (every 8 weeks) in an effort to recapture his/her remission. Please note, the FDA labelling of infliximab gives the treating specialist the option of dose escalation to 10mg/kg.

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 infliximab [Month/Year of induction] and has done well on infliximab 5 mg/kg every 8 weeks maintenance therapy. Unfortunately, since [Date of flare symptoms] Mr./Ms. Doe has developed increasing symptoms of active disease [can also add pertinent colonoscopy, CRP, calprotectin, or infliximab level data here] despite ongoing treatment with infliximab at standard dosing. Given his/her previous medication failures, initial clinical response to infliximab therapy, and ongoing active inflammation, I am requesting approval for an increase to infliximab 10 mg/kg q8 weeks.

Regueiro et al1 studied Crohn’s disease patients who required dose intensification, defined as either an increase in infliximab dose, or a decrease in infusion interval. At 30-months from initial infusion, 69.1% of all patients were event-free from an interval decrease, 48.5% were event-free from a dose increase, and 45.7% were event-free for dose intensification.

Shih et al2 did a retrospective analysis of Crohn’s patients who received infliximab over a five-year period. Forty eight percent (48%) of patients required an increase in dosage and/or a decrease in interval to maintain response: specifically, a dose increase to 10 mg/kg to maintain response in 32% of patients, and a decrease in interval in 27% of patients.

These data confirm that the need for infliximab 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 infliximab. 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 infliximab.

Based on the data presented in this letter and my professional experience, I am advocating that dose-escalated Infliximab 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

Regueiro M, Siemanowski B, Kip K, et al. Infliximab dose intensification in Crohn’s disease. *Inflamm Bowel Disease*. Published online first May 4, 2007; doi:10.1002/ibd.20177.

Shih GE, Bayless TM, Harr ML. Maintenance of long term response to infliximab over 1 to 5 years in Crohn’s Disease including shortening dosing intervals or increasing dosage. [Abstract]. *Digestive Disease Week*, May 16-19, 2004. New Orleans, LA. Abstract 104672.

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