SAMPLE APPEAL LETTER – CERTOLIZUMAB PEGOL 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 a dose escalation of certolizumab pegol.

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 responded to the induction dosing with certolizumab pegol and then lost response after being on maintenance doses for XXXX months/years. He/She is now experiencing symptoms of a Crohn’s disease flare with X loose stools per day, abdominal pain, fevers, (describe of symptoms). His/her most recent evaluation includes: (notable labs/scopes/stool studies) which indicates his/her active disease. The most appropriate course of action would be to dose escalate certolizumab to enable Mr./Ms. Doe to recapture his/her response and avoid steroids, hospitalizations, or surgery, which are associated with higher costs of care.

Data from a group of patients who lost response during the PRECiSE clinical trials1 suggest that a single re-induction dose with certolizumab pegol 400 sc mg may re-establish response in this group of patients. Please note: This has been well described in the published literature:

From **Sandborn et al. Gastroenterol Hepatol. 2008;4(7)467-8**2**:** "In extension trials with certolizumab pegol, where patients responded, but then lost response, the strategy was to re-induce with certolizumab pegol 400 mg at 0, 2, and 4 weeks, and then return to every-4-week dosing at 400 mg, rather than increase the dose, or shorten the dosing interval. Because the maintenance regimen with certolizumab pegol is 400 mg every 4 weeks, this strategy requires only one extra 400 mg dose between two maintenance doses. Using this reinduction strategy, approximately one third of patients who had lost response were able to regain and maintain it. It is interesting that one third of patients will respond in this situation, simply by giving one extra dose ... a dosing strategy of 400 mg every 2 weeks may regain response in even more patients. Although the reinduction strategy is a useful starting point for this patient population, sustained dose escalation or interval shortening [may] regain response in an even larger percentage of these patients."

Mr./Ms. Doe has been on cetrolizumab pegol with demonstrated efficacy, and absence of major adverse events. We ask that you approve this request for dose escalation of certolizumab pegol as soon as possible, in order to allow Mr./Ms. Doe to maintain his/her quality of life, continue his/her daily activity free from the symptoms of moderate to severe Crohn’s disease. Data from the WELCOME trial revealed that higher rates of remission were achieved in patients with drug levels in the two highest quartiles3,4,5.

Please contact me at if any additional information will help clarify this request.

Sincerely,

Dr.

Address

Contact Info

References:

1. [Lee SD](file:///C:/pubmed/), [Rubin DT](file:///C:/pubmed/), [Sandborn WJ](file:///C:/pubmed/), [Randall C](file:///C:/pubmed/), [Younes Z](file:///C:/pubmed/), [Schreiber S](file:///C:/pubmed/), [Schwartz DA](file:///C:/pubmed/), [Burakoff R](file:///C:/pubmed/), [Dassopoulos T](file:///C:/pubmed/), [Arsenescu R](file:///C:/pubmed/), [Gutierrez A](file:///C:/pubmed/), [Scherl E](file:///C:/pubmed/), [Kayhan C](file:///C:/pubmed/), [Hasan I](file:///C:/pubmed/), [Kosutic G](file:///C:/pubmed/), [Spearman M](file:///C:/pubmed/), [Sen D](file:///C:/pubmed/), [Coarse J](file:///C:/pubmed/), [Hanauer S](file:///C:/pubmed/). **Reinduction with Certolizumab Pegol in Patients with Crohn's Disease Experiencing Disease Exacerbation: 7-Year Data from the PRECiSE 4 Study**. [*Inflamm Bowel Dis.*](file://l)2016 Aug;22(8):1870-80
2. [Sandborn WJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Sandborn%20WJ%5BAuthor%5D&cauthor=true&cauthor_uid=20363366), [Schreiber S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Schreiber%20S%5BAuthor%5D&cauthor=true&cauthor_uid=20363366), [Hanauer SB](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hanauer%20SB%5BAuthor%5D&cauthor=true&cauthor_uid=20363366), [Colombel JF](https://www.ncbi.nlm.nih.gov/pubmed/?term=Colombel%20JF%5BAuthor%5D&cauthor=true&cauthor_uid=20363366), [Bloomfield R](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bloomfield%20R%5BAuthor%5D&cauthor=true&cauthor_uid=20363366), [Lichtenstein GR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Lichtenstein%20GR%5BAuthor%5D&cauthor=true&cauthor_uid=20363366); [PRECiSE 4 Study Investigators](https://www.ncbi.nlm.nih.gov/pubmed/?term=PRECiSE%204%20Study%20Investigators%5BCorporate%20Author%5D). Reinduction with certolizumab pegol in patients with relapsed Crohn's disease: results from the **PRECiSE 4 Study.** [*Clin Gastroenterol Hepatol.*](file://l) 2010 Aug;8(8):696-702.e1. doi: 10.1016/j.cgh.2010.03.024. Epub 2010 Apr 2.
3. Roda, g Jharap B, Neeraj N, Columbel J; Loss of Response to Anti-TNFs: Definition, Epidemiology, and Management. Clin Transl gastroenterol. 2016 Jan;7(1):e135.
4. Lichtenstin G. Comprehensive review: antitumor necrosis factor agents in inflammatory bowel disease and factors implicated in treatment response. Therapeutic Advances inGastroenterology. 2013 Jul; 6(4): 269-293.
5. Sandborn, W, Abreu M, D’Haens G, Colombel J, Bermeire S, Mitchev K et al. Certolizumab Pegol in patients with moderate to severe Crohns disease and secondary failure to infliximab. Clin Gastroenterology Hepatology 8: 688-695.