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SAMPLE APPEAL LETTER – TOFACITINIB DOSE ESCALATION

Insurance Company

# RE: PATIENT

**DOB:**

**ID #**

**Pat Acct #**

DATE

Dear Sir, or Madam:

I am writing on behalf of PATIENT NAME to appeal the denied coverage of tofacitinib 10 mg twice a day. The initial request was denied due to “XXX.”

PROVIDE INFORMATION ABOUT PATIENT

* DIAGNOSIS, YEAR DIAGNOSED
* PRIOR TREATMENTS TRIED AND WHY TREATMENT DID NOT WORK
* DOCUMENTATION OF CLINICAL OR ENDOSCOPIC REMISSION ON TOFACITINIB10 MG BID

While tofacitinib 10mg twice a day is approved for induction, with the recommendation to transition to 5mg twice a day for maintenance, this patient is a multi-drug refractory patient who is in endoscopic and histologic remission on the higher does. Risks and benefits of this drug have been thoroughly discussed and there is significant concern that dose de-escalation to 5mg twice a day could lead to disease worsening, loss of response and inability to recover response or remission when increasing the dose back up. The FDA has not mandated that patients reduce tofacitinib to twice daily, but rather suggests that the lowest effective dose is used. Tofacitinib 10mg twice a day is the lowest effective dose at this time.

There is evidence that dose de-escalation is not appropriate for every patient. The OCTAVE Open trial (an ongoing, open label, long-term extension of the Phase 3 trials) examined the response to tofacitinib dose escalation to 5 mg twice daily after maintaining remission at week 52 on 10 mg twice daily. The study also examined patients who lost response to 5mg twice daily and their rate of recapture after increasing the dose back up to 10 mg twice daily. While most patients in remission on 10 mg twice daily maintained remission after decreasing the dose, **25.4% lost remission by month 12.** Furthermore, in the other study arm of patients who lost response to 5mg twice daily, **only 49.1% were able to achieve remission after increasing the dose again.** This represents a significant number of patients unable to recapture response despite escalation back to 10mg twice daily1

Per the RIVETING trial, a randomized study in which patients on tofactibinib 10 mg PO BID were randomized to either 5 or 10 mg BID, 20% of participants flared with the dose decrease to 5 mg BID and more importantly, not all participants were able to recapture response or remission with the re-increase to 10 mg PO BID. Moreover, of the participants who dose de-escalated, those with deep endoscopic remission and without prior tumor necrosis inhibitor failure were more likely to maintain remission.2

These studies collectively highlight that certain individuals with ulcerative colitis experience disease worsening with reduction to tofacitinib 5 mg BID dosing and would benefit from continuation of the 10 mg BID dosing for optimal disease control.

Based on the information presented in this letter and my professional experience, I am advocating that Xeljanz 10 mg PO twice daily be continued and covered for PATIENT NAME. **An urgent review and approval is requested to minimize disruption in treatment and need for hospitalization and surgery if a UC flare is to occur.**

I appreciate your consideration in this matter. Please feel free to contact my office if any additional information will help clarify this request.

Sincerely,

MD NAME

References:

1. Sands BE, Armuzzi A, Marshall JK, et al. Efficacy and safety of tofacitinib dose de-escalation and dose escalation for patients with ulcerative colitis: results from OCTAVE Open. *Aliment Pharmacol Ther*. 2020;51(2):271-280. doi:10.1111/apt.15555
2. Vermeire S, Su C, Lawendy N, et al. Outcomes of Tofacitinib Dose Reduction in Patients with Ulcerative Colitis in Stable Remission from the Randomised RIVETING Trial. *J Crohns Colitis*. 2021;15(7):1130-1141. doi:10.1093/ecco-jcc/jjaa249