Insurance Company

# RE:

**DOB:**

**ID #**

**Pat Acct #**

DATE

Dear Sir, or Madam:

I am writing on behalf of my patient, Mr./Ms. Doe, to request off label use of XXX for the treatment of his/her inflammatory bowel disease.

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].

As this patient has failed XXXXX for his/her inflammatory bowel disease and is at high risk to suffer substantial disability from his/her disease, I am urging you to approve coverage of XXX drug. I am enclosing references below of peer-reviewed medical literature that demonstrates that the use of XXX for the treatment of XXX.

In 1982, the FDA issued a Drug Bulletin addressing the prescribing of medication for “unlabeled” or off-label uses, FDA Drug Bulletin, Volume 12, Number 1, pages 4-5 (April 1982). The FDA itself states that the Food, Drug and Cosmetic Act “does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses, or in treatment regimens, or patient populations that are not included in approved labeling. Such ‘unapproved’ or, more precisely, ‘unlabeled’ uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.”

The term “unapproved uses” is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to the FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. If the FDA itself states that its labeling is not intended to limit the prescribing of medications for off-label uses, then insurers should not be permitted to refuse coverage of off-label uses solely based on the fact that the use is off-label. Clearly, such a result would run contrary to the FDA’s own intent regarding the effect of its labeling. Furthermore; given this is a lifelong chronic disease without a cure and an overall limited amount of drugs available we want to optimize to the best of our capabilities the current medication at an altered frequency to prevent us from moving on and having to start another medication.

Furthermore, there may be safety concerns as data suggest that up to 60% of patients may be able to restart biologics after a drug holiday. This data has primarily been performed in the infliximab and adalimumab populations and that should call to mind the possibility that 40% of patients may not be able to restart after a drug holiday with safety concerns if these patients develop antibodies1.

Many drugs, including 6-mercaptopurine, mesalamine, and methotrexate, are used to treat inflammatory bowel disease. These drugs are used off-label, without FDA approval for this use. Yet, these drugs are covered by insurers.

My patient has failed XXXXX for his/her IBD at this time and is at risk to suffer from significant and costly complications related to his/her disease without effective therapy. I believe it is likely that XXX will provide a beneficial outcome for my patient and would propose a 3-6month trial of this medication with reevaluation of symptoms and objective measures of disease activity at that time with continued coverage dependent on its efficacy.

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

1. Rubin D. Restarting biologic agents after a drug holiday. Gastroenterology and Hepatology. [Gastroenterol Hepatol (N Y)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6883732/). 2019 Nov; 15(11): 612–615.