Insurance Company

# RE: PATIENT/Vedolizumab infusions

**DOB:**

**ID #**

**Pat Acct #**

DATE

Dear Sir/Madam:

I write to you on behalf of <Mr./Ms. Doe> to request prior authorization/approval for vedolizumab for the treatment of their <moderately/severely> active <Crohn's disease/ulcerative colitis>. Below is the detailed medical information to support the use of vedolizumab to help <Mr./Ms. Doe> achieve remission.

<Mr./Ms. Doe> has presented with <*insert clinical information*>. <*Examples include:*

* Primary non-response to an anti-TNF therapy
* Other patient attributes that make it preferable to consider vedolizumab prior to anti-TNF therapy, such as safety or intolerance or contraindications for anti-TNF>

Vedolizumab is a distinct mechanism from anti-TNF therapies. It is a gut-selective alpha4beta7 anti-integrin antibody. As such, it is appropriate for many patients both for its unique mechanism of action, as well as for its favorable, nonsystemic safety profile. There are distinct patient populations in whom it is preferable to consider this therapy prior to anti-TNF therapy. In addition, it is appropriate to switch mechanisms of management when there is a primary non-response to the first anti-TNF therapy, or when the current anti-TNF therapy is not adequately controlling inflammation.

In large clinical trials, vedolizumab was effective in both anti-TNF naïve (no prior anti-TNF therapy) and in anti-TNF experienced patients. The Food and Drug Administration (FDA) approved the use of vedolizumab in both Crohn’s disease and ulcerative colitis patients. In addition, failure of anti-TNF is not required prior to using vedolizumab. This is an important distinction.

Medical care is adversely affected by policies that limit access to anti-integrin therapies by affecting medical decisions, and by interrupting the decision-making process between the physician and patient. <*Optional based on the insurer grounds for refusal to cover:* Policies that a) require Crohn’s disease and ulcerative colitis patients to fail two anti-TNF therapies prior to being provided access are both unnecessary and potentially harmful and costly. A significant number of patients failing to respond or losing response to an anti-TNF therapy are doing so because of mechanism failure. In such situations, exposing such patients to a second drug within the same class is medically incorrect, and would be considered in many cases unethical, with the likelihood of damage and disease progression outweighing any benefits. It is also highly likely to be cost ineffective for both direct (costs of drug and escalation of care) and indirect (costs of lost work/school, and progression of disease) reasons. Or b) require unnecessary infectious disease testing that is costly, and delay the time this therapy can be started. Testing for <hepatitis B and/or tuberculosis is not indicated, was not in the label, has not been supported by any safety evidence, and is also both expensive and unnecessary. In fact, Colombel *et al.* (Gut 2017;66:839-51) found no increased risk of TB in patients receiving vedolizumab, compared to the general population. Several studies have now shown no increased risk of Hepatitis B reactivation in patients on vedolizumab (Colombel JF. Gut 2017;66:839-51; Wu DC. P1315; ACG2017) >

Please approve this request for vedolizumab, and allow <Mr./Ms. Doe> to return to a productive life free from the symptoms of moderate to severe <Crohn’s disease or ulcerative colitis>.

Please contact me at (xxx) xxx-xxxx if any additional information will help clarify this request.

Sincerely,

Dr.

Address

Contact Info