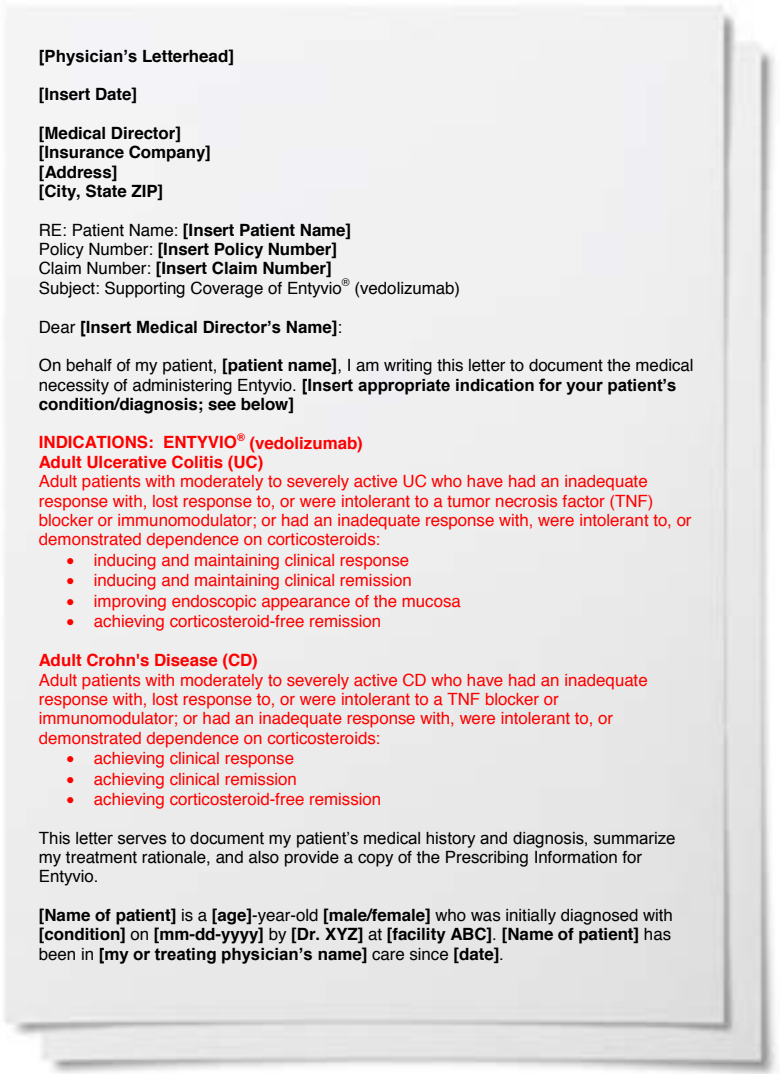
7 SAMPLE LETTER OF MEDICAL NECESSITY

Some payers may require that the healthcare provider or infusion center submit a letter or statement of medical necessity for Entyvio. The following is an example letter that outlines information that a payer may request.

SUGGESTED EXAMPLE FOR USE:

- Make sure to replace all bracketed information with the appropriate office and patient information
- Use the text in red to help determine the appropriate indication to include for your patient's condition/diagnosis
- Include the Entyvio package insert with your letter, along with any other supporting documentation
- Refer back to the prior authorization-specific instructions you received from your case manager team and/or insurance provider

Click here for a customizable sample letter of medical necessity.



[Physician's Letterhead]

[Insert Date]

[Medical Director]
[Insurance Company]
[Address]
[City, State ZIP]

RE: Patient Name: **[Insert Patient Name]**
Policy Number: **[Insert Policy Number]**
Claim Number: **[Insert Claim Number]**
Subject: Supporting Coverage of Entyvio® (vedolizumab)

Dear **[Insert Medical Director's Name]**:

On behalf of my patient, **[patient name]**, I am writing this letter to document the medical necessity of administering Entyvio. **[Insert appropriate indication for your patient's condition/diagnosis; see below]**

INDICATIONS: ENTYVIO® (vedolizumab)
Adult Ulcerative Colitis (UC)
Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- inducing and maintaining clinical response
- inducing and maintaining clinical remission
- improving endoscopic appearance of the mucosa
- achieving corticosteroid-free remission

Adult Crohn's Disease (CD)
Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- achieving clinical response
- achieving clinical remission
- achieving corticosteroid-free remission

This letter serves to document my patient's medical history and diagnosis, summarize my treatment rationale, and also provide a copy of the Prescribing Information for Entyvio.

[Name of patient] is a **[age]**-year-old **[male/female]** who was initially diagnosed with **[condition]** on **[mm-dd-yyyy]** by **[Dr. XYZ]** at **[facility ABC]**. **[Name of patient]** has been in **[my or treating physician's name]** care since **[date]**.

For questions, please call **1-855-ENTYVIO** (1-855-368-9846), Monday to Friday, from 8 AM to 8 PM EST (except holidays)

Please see Indications and Important Safety Information on next page.

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IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.
- Infusion-related reactions and hypersensitivity reactions including anaphylaxis have occurred. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

IMPORTANT SAFETY INFORMATION (continued)

- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.
- Although no cases of PML have been observed in ENTYVIO clinical trials, JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.
- Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.
- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please click here to read the full Prescribing Information, including Medication Guide.

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