PRIOR AUTHORIZATION (PA) CHECKLIST

FOR ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC) OR CROHN'S DISEASE (CD).

Entyvio® vedolizumab

PA requirements vary by health plan. Contact the patient's health plan to understand the specific PA requirements and specified submission protocol (typically phone, fax, or web submission).

For ulcerative colitis (UC) patients only: PAs for self-administered subcutaneous (SC) injections with the ENTYVIO Pen are typically processed under a patient's pharmacy benefit. If this is the case, submit the PA 2-4 weeks before their next scheduled infusion date.

Collect the following information prior to submitting the PA as these items may be necessary to obtain a PA decision from a health plan:

- ☐ Patient name, insurance policy number, and date of birth
- ☐ Ordering physician's name, contact information, tax ID, and NPI #
- ☐ Treatment facility name, contact information, and tax ID
- ☐ Date of service
- ☐ Patient diagnosis (ICD-10-CM code[s]) as well as relevant procedure and HCPCS codes if applicable for services/products to be performed/provided
- ☐ Product NDC
- ☐ Any additional information specified by the health plan

A PA request may also benefit from including a letter of medical necessity. Refer to our sample.

Track the following throughout the submission process:

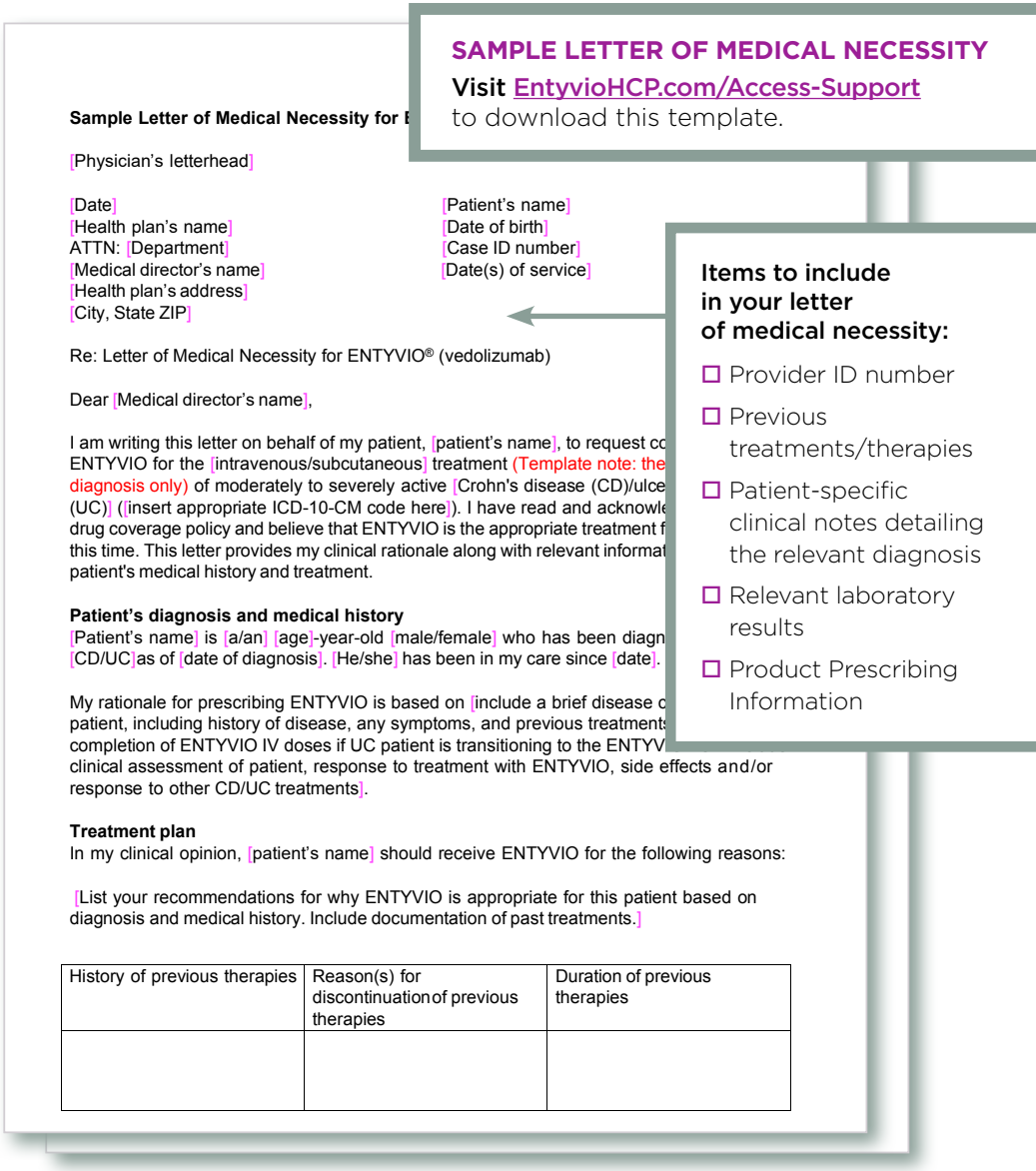
- ☐ Dates and methods of correspondence (phone, written, fax, and web)
- ☐ Names of insurance contacts and reviewers
- ☐ Summaries of conversations and copies of written documents from insurer
- ☐ Reference numbers from phone conversations

Please contact your Field Reimbursement Manager or *EntyvioConnect* if you need additional education at any step in the process.

Please see Important Safety Information on the next page.

SAMPLE LETTER OF MEDICAL NECESSITY

Visit EntyvioHCP.com/Access-Support to download this template.



Sample Letter of Medical Necessity for E

[Physician's letterhead]

[Date]
[Health plan's name]
ATTN: [Department]
[Medical director's name]
[Health plan's address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Case ID number]
[Date(s) of service]

Re: Letter of Medical Necessity for ENTYVIO® (vedolizumab)

Dear [Medical director's name],

I am writing this letter on behalf of my patient, [patient's name], to request co
ENTYVIO for the [intravenous/subcutaneous] treatment (Template note: the
diagnosis only) of moderately to severely active [Crohn's disease (CD)/ulce
(UC)] ([insert appropriate ICD-10-CM code here]). I have read and acknowle
drug coverage policy and believe that ENTYVIO is the appropriate treatment f
this time. This letter provides my clinical rationale along with relevant informat
patient's medical history and treatment.

Patient's diagnosis and medical history
[Patient's name] is [a/an] [age]-year-old [male/female] who has been diagn
[CD/UC] as of [date of diagnosis]. [He/she] has been in my care since [date].

My rationale for prescribing ENTYVIO is based on [include a brief disease c
patient, including history of disease, any symptoms, and previous treatments
completion of ENTYVIO IV doses if UC patient is transitioning to the ENTYV
clinical assessment of patient, response to treatment with ENTYVIO, side effects and/or
response to other CD/UC treatments].

Treatment plan
In my clinical opinion, [patient's name] should receive ENTYVIO for the following reasons:

[List your recommendations for why ENTYVIO is appropriate for this patient based on diagnosis and medical history. Include documentation of past treatments.]

History of previous therapies	Reason(s) for discontinuation of previous therapies	Duration of previous therapies

Items to include in your letter of medical necessity:

- ☐ Provider ID number
- ☐ Previous treatments/therapies
- ☐ Patient-specific clinical notes detailing the relevant diagnosis
- ☐ Relevant laboratory results
- ☐ Product Prescribing Information

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- **Infections:** 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.
- **Progressive Multifocal Leukoencephalopathy (PML):** PML, a rare and often fatal opportunistic infection of the central nervous system (CNS), has been reported with systemic immunosuppressants, including another integrin receptor antagonist. PML typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported. Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms that may 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 neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- **Liver Injury:** 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.
- **Live and Oral Vaccines:** 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.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥3% and ≥1% higher than placebo) were: nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, pain in extremities, and injection site reactions with subcutaneous administration.

DRUG INTERACTIONS

Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYVIO with natalizumab products and with TNF blockers.

INDICATIONS

Adult Ulcerative Colitis (UC):

ENTYVIO is indicated in adults for the treatment of moderately to severely active UC.

Adult Crohn's Disease (CD):

ENTYVIO is indicated in adults for the treatment of moderately to severely active CD.

DOSAGE FORMS & STRENGTHS:

- ENTYVIO Intravenous (IV) Infusion: 300 mg vedolizumab
- ENTYVIO Subcutaneous (SC) Injection: 108 mg vedolizumab

Please click for Full Prescribing Information.

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