PRIOR AUTHORIZATION (PA) DENIAL AND APPEAL CHECKLIST

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

Entyvio® vedolizumab

PA denials and appeals vary by health plan. These processes can be conducted through letter correspondence, fax, or peer-to-peer discussion.

For the ENTYVIO Pen: PAs for self-administered subcutaneous (SC) injections with the ENTYVIO Pen are typically processed under a patient's pharmacy benefit. Therefore, it is recommended to submit the PA [2-4 weeks] before their next scheduled infusion date. **A PA may be denied if a patient has not yet completed at least 2 intravenous (IV) doses.**

The following information may be helpful in appealing a PA denial.

If the health plan has denied a PA for ENTYVIO:

- ☐ Review the denial notification so your appeal can address the specific reasons for the denial
  - ☐ Contact the insurer if you have not received a denial explanation
  - ☐ Confirm with the insurer where the appeal should be sent
  - ☐ Confirm any deadlines
- ☐ Gather the necessary documents and information (eg, chart details, lab values, anything applicable to the specific reason for denial)

If you or your patient has not received a decision within 30 days:

- ☐ Contact the health plan to confirm that the appeal letter was received and ask about its status
- ☐ An urgent review of the appeal may be available upon request

If the first appeal was denied:

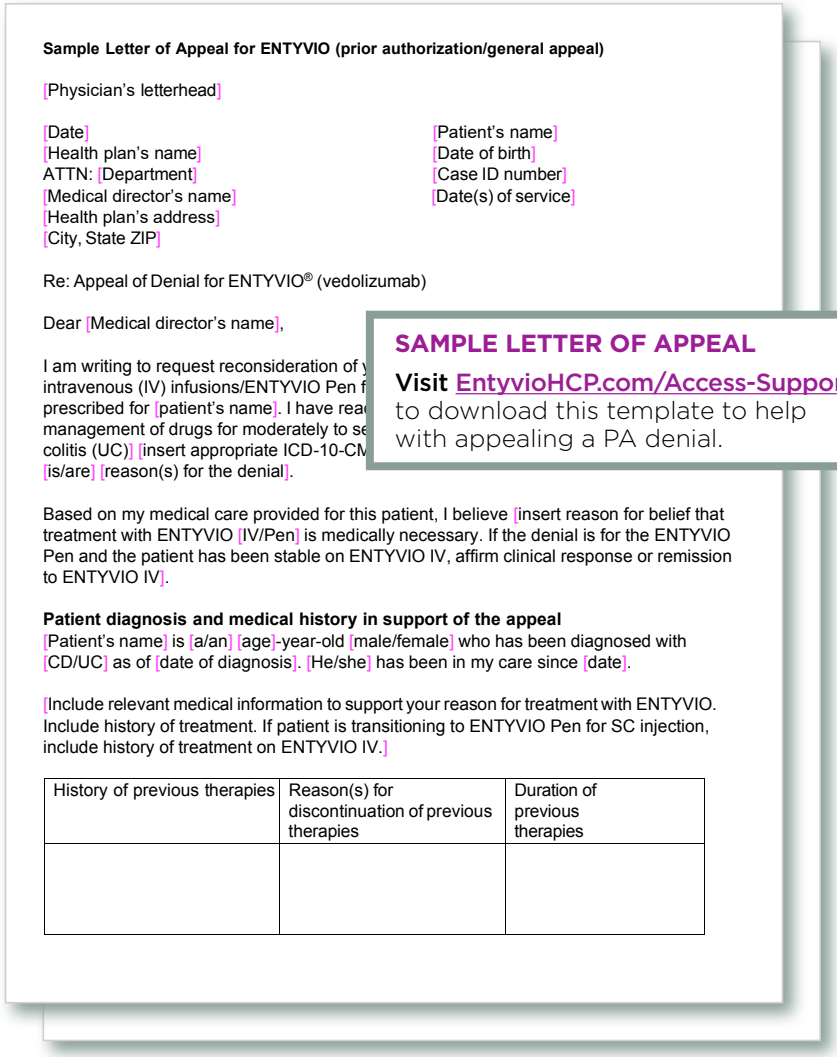
- ☐ Contact the health plan to understand the next level of appeal and if any additional information is required

If the appeal process has been exhausted with the insurer, consider the following alternatives:

- ☐ Ask for a supervisor or manager to assist
- ☐ Ask for a one-time exception
- ☐ File a complaint with the state's insurance commissioner
- ☐ Submit a request for an external review

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 Appeal for ENTYVIO (prior authorization/general appeal)

[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: Appeal of Denial for ENTYVIO® (vedolizumab)

Dear [Medical director's name],

I am writing to request reconsideration of y
intravenous (IV) infusions/ENTYVIO Pen f
prescribed for [patient's name]. I have rea
management of drugs for moderately to se
colitis (UC)] [insert appropriate ICD-10-CM
[is/are] [reason(s) for the denial].

Based on my medical care provided for this patient, I believe [insert reason for belief that treatment with ENTYVIO [IV/Pen] is medically necessary. If the denial is for the ENTYVIO Pen and the patient has been stable on ENTYVIO IV, affirm clinical response or remission to ENTYVIO IV].

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

[Include relevant medical information to support your reason for treatment with ENTYVIO. Include history of treatment. If patient is transitioning to ENTYVIO Pen for SC injection, include history of treatment on ENTYVIO IV.]

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

SAMPLE LETTER OF APPEAL

Visit EntyvioHCP.com/Access-Support to download this template to help with appealing a PA denial.

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. Upon initiation or discontinuation of ENTYVIO in patients treated with CYP450 substrates, monitor drug concentrations or other therapeutic parameters, and adjust the dosage of the CYP substrate as needed.

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.

US-VED-2389v2.0 05/24