ENTYVIO Insurance Approval Process

Entyvio® CONNECT
vedolizumab

ENTYVIO treatment begins with IV infusions, with the option to transition to ENTYVIO Pen for maintenance following initiation

1 Complete a benefits investigation/verification

When your patient is first prescribed ENTYVIO, perform a benefits investigation/verification (BI/BV) **for both ENTYVIO IV and/or Pen** through your standard process or by submitting the *EntyvioConnect* Patient Enrollment Form. The BI/BV will detail your patient's insurance coverage.

If your patient is an established ENTYVIO IV patient, upon completing the BI/BV for ENTYVIO Pen, skip to number 3

2 Initiate ENTYVIO IV

- The infusion site or your practice must submit a prior authorization (PA) for ENTYVIO IV in accordance with the patient's insurance requirements. **ENTYVIO IV is typically covered under the medical benefit**
- **Schedule and complete** your patient's IV initiation doses or refer them to an in-network infusion center to begin treatment. Your dedicated ENTYVIO support team can assist with identifying a treatment site for your patient

3 Send your patient's ENTYVIO Pen prescription to an SP

ENTYVIO has an open specialty pharmacy (SP) network, which means your practice has the flexibility to send your patient's prescription to any SP, as long as it is approved by your patient's insurance provider.

Scan code to explore ENTYVIO Pen Preferred SP Partners.

4 Coordinate with the SP

The SP will manage the insurance approval, including submission of the PA for ENTYVIO Pen, and will coordinate with your practice as needed.

- Your practice may have to provide additional information, if required, such as **rationale for transition (eg, continuity of care or initiation of maintenance therapy)** and prior treatment history

ENTYVIO treatment for eligible patients starting at $0*

Co-Pay Program can help eligible patients with commercial insurance pay as little as **$0 per dose** of ENTYVIO up to a total benefit of $20,000 per year.*

Start Program can help your commercial patients start on ENTYVIO fast during insurance delays for **$0 up to 3 years**.*

Bridge Program helps your patients stay on track at **no cost** during gaps in commercial insurance coverage for **up to 6 months**.*

Patient Assistance Program helps patients with no health insurance or those whose benefits are insufficient to cover ENTYVIO and there is an identified financial need.*

*Terms and conditions apply. Must meet eligibility requirements.

Visit EntyvioHCP.com or scan the QR code to learn more.

Advise the patient that the SP will contact them to confirm delivery and payment details once approved. Upon approval, ENTYVIO Pen will be shipped directly to your patient's home.

If you have any questions about your patient's coverage, please connect with your local ENTYVIO Field Access Manager or *EntyvioConnect* Case Manager at 1-855-ENTYVIO (1-855-368-9846) Monday to Friday, 8 AM to 8 PM ET.

ENTYVIO is indicated for adult patients with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD).

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.

Please see additional Important Safety Information on page 2.

ENTYVIO Insurance Approval Process

Entyvio® CONNECT vedolizumab

1. **Complete a benefits investigation/verification**
2. **Initiate ENTYVIO IV**
3. **Send your patient's ENTYVIO Pen prescription to an SP**
4. **Coordinate with the SP**

If you have any questions about your patient's coverage, please connect with your local ENTYVIO Field Access Manager or *EntyvioConnect* Case Manager at 1-855-ENTYVIO (1-855-368-9846) Monday to Friday, 8 AM to 8 PM ET.

IMPORTANT SAFETY INFORMATION (continued)

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:** ENTYVIO increases the risk for developing infections. Serious infections in clinical trials included anal abscess, sepsis (some fatal), tuberculosis (TB), salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. Postmarketing reports include systemic bacterial, fungal, viral, and parasitic opportunistic infections.
  Do not start ENTYVIO in patients with a clinically important active infection until resolved or adequately treated. In patients with chronic infection or history of recurrent infection, consider risks and benefits prior to ENTYVIO. Instruct patients to seek medical advice if signs or symptoms of acute or chronic infection occur. If a serious infection develops or does not respond to therapy, monitor closely and do not administer ENTYVIO until resolved.
  Tuberculosis: Consider evaluating for TB prior to ENTYVIO. Do not administer ENTYVIO to patients with active TB. Before starting ENTYVIO, treat latent TB and consider anti-TB therapy in patients with a history of TB if adequate course of treatment cannot be confirmed. Monitor for active TB during and after ENTYVIO.
- **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.
- **Immunizations:** 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

ENTYVIO is indicated in adults for the treatment of:

- moderately to severely active ulcerative colitis (UC)
- moderately to severely active Crohn's disease (CD)

DOSAGE FORMS & STRENGTHS

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

Please see additional IMPORTANT SAFETY INFORMATION on page 1 and click for Full Prescribing Information.

If you are a Colorado prescriber, please see the WAC disclosure form at Takeda.info/ENTYVIOCOPricing.
If you are a Connecticut prescriber or pharmacist, please see the WAC disclosure form at Takeda.info/ENTYVIOCTPricing.

Takeda