Entyvio®
vedolizumab

For patients with moderate to severe ulcerative colitis (UC) or Crohn's disease (CD)

FROM PRESCRIBING TO TREATING

A Guide to Acquiring the ENTYVIO Pen for Subcutaneous (SC) Injection

INDICATIONS

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 6.

GETTING THE NECESSARY APPROVALS

Entyvio® vedolizumab

After you've prescribed ENTYVIO, the first step is to verify that your patient's health insurance covers the drug before initiating treatment. If your patient wants to switch to the ENTYVIO Pen and is currently receiving and responding to ENTYVIO intravenous (IV) therapy after Week 6, you can skip to the next page.

IF YOU PLAN TO ADMINISTER ENTYVIO IV, YOUR OFFICE USUALLY IS RESPONSIBLE FOR:

- Checking benefits
- Submitting a prior authorization (PA) before the first initiation dose is scheduled
- Handling any relevant denials and appeals
- Managing co-pay benefits
- Obtaining the prescription ahead of scheduled infusions

IF YOU SEND YOUR PATIENT TO AN ALTERNATE SITE OF CARE (ASOC) FOR THEIR INFUSIONS, THE ASOC TYPICALLY HANDLES:

- The insurance verification and approval process
- Obtaining the prescription ahead of scheduled infusions

The ENTYVIO Infusion Center Locator allows healthcare providers to tailor their patients' treatment experience by searching for criteria such as proximity, operating hours, accepted insurance, and specific amenities.

After you've prescribed ENTYVIO, you can enroll new patients in *EntyvioConnect* for help with the entire insurance approval process. Go to EntyvioHCP.com to get started.

MAPPING IT OUT

Entyvio® vedolizumab

All patients new to ENTYVIO start treatment with at least 2 IV initiation doses. ENTYVIO may be switched from IV to SC for patients currently receiving and responding to ENTYVIO IV therapy after Week 6. How this occurs depends on whether they are just starting treatment or are already on IV maintenance.

Example Prescriptions of ENTYVIO IV and ENTYVIO Pen

START

Start with 300 mg IV infusions for:

Weeks 0 and 2

Rx: ENTYVIO 300 mg IV
Sig: 1 IV infusion Q2W
Disp: 2 IV doses
Refills: 0

For IV doses, submit a medical benefit prior authorization (PA) 2-4 weeks before first infusion date.

MAINTAIN

Starting at Week 6, continue with infusions every 8 weeks

Rx: ENTYVIO 300 mg IV
Sig: 1 IV infusion Q8W
Disp: 1 IV dose
Refills:

ENTYVIO may be switched from IV to SC for patients currently receiving and responding to ENTYVIO IV therapy after Week 6.

Starting at Week 6, begin ENTYVIO SC 108 mg and continue every 2 weeks

For patients who have received 2 or more IV doses, administer the first SC dose in place of the next scheduled IV infusion.

Rx: ENTYVIO Pen 108 mg
Sig: 1 single-dose prefilled pen Q2W
Disp: 2 SC pens
Refills:

To transition patients to ENTYVIO SC, start the pharmacy benefit PA process 2-4 weeks before the next scheduled infusion date.

Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.

Monitoring

ENTYVIO IV should be administered by a healthcare professional prepared to manage hypersensitivity reactions, including anaphylaxis, if they occur. Appropriate monitoring and medical support measures should be available for immediate use. Observe patients during infusion and until the infusion is complete.

Injection education

After proper training on correct SC injection technique, a patient or caregiver may inject ENTYVIO SC if a healthcare professional determines it is appropriate. Patients and caregivers should be instructed to follow the directions for administration of ENTYVIO SC in the Instructions for Use section of the Prescribing Information.

When your patient is ready to transition to the ENTYVIO Pen, submit a new *EntyvioConnect* enrollment form and select the SC prescription. This step is required because coverage may move from medical benefit to pharmacy benefit. We can then identify specialty pharmacies (SPs) in our network and ensure patients prescribed the ENTYVIO Pen have access to additional resources relevant to their treatment.

SELECTED SAFETY INFORMATION

- If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

Q2W=every 2 weeks; Q8W=every 8 weeks.

Reference: ENTYVIO (vedolizumab) prescribing information. Takeda Pharmaceuticals.

Please see additional Important Safety Information on page 6.

SENDING IT TO THE SPECIALTY PHARMACY

ENTYVIO Pen prescriptions are filled by a network of SPs. Here are some things to keep in mind before and after you send the prescription.

BEFORE YOU SEND THE PRESCRIPTION:

- Check the SP information sheet, which has the current list of SPs in the distribution network
- Cross-check the SPs on the sheet against the ones in your patient's pharmacy network
- Confirm coverage under the pharmacy benefit, complete any required prior authorizations, and send the SP an electronic prescription for the single-dose prefilled pen

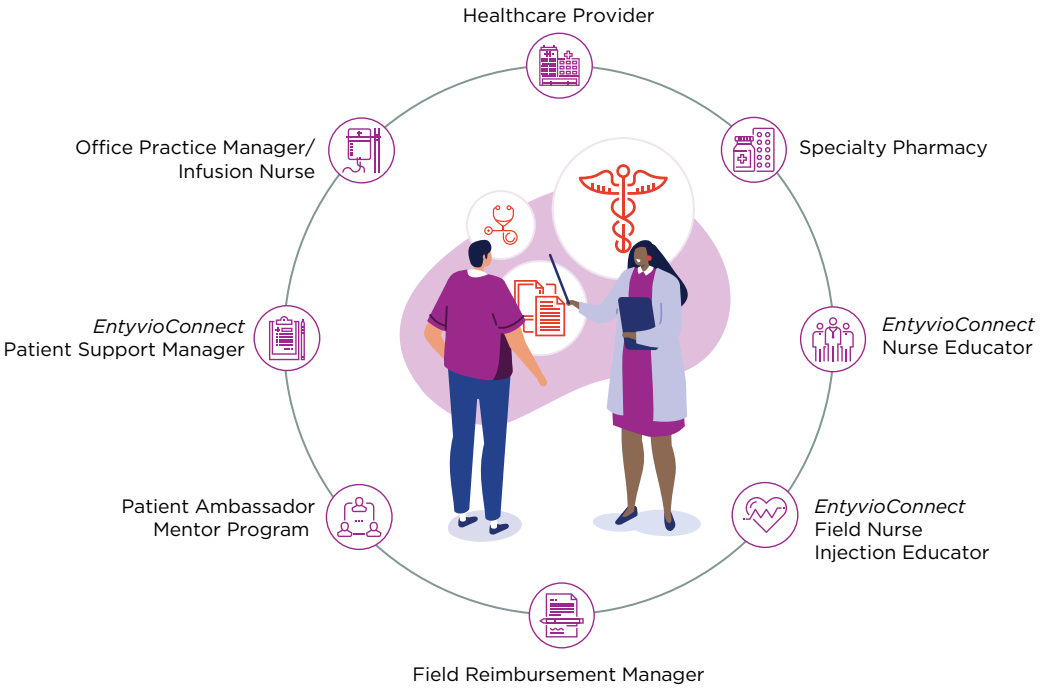
AFTER YOU SEND THE PRESCRIPTION:

- Let patients know that someone from the SP will likely be contacting them to confirm details like shipping address and to discuss financial benefit requirements if applicable

PREPPING FOR THE ENTYVIO PEN

It is recommended that patients receive injection education prior to using the ENTYVIO Pen. Before your patient starts their ENTYVIO Pen treatment, re-enroll them in *EntyvioConnect*. That way, they can opt in to be paired with a Nurse Educator for virtual or in-home injection education, which they should complete before starting SC treatment. Through *EntyvioConnect*, patients can also request a kit to help them get started.

PATIENT SUPPORT ALONG THE WAY



THE KIT

- A TRAINING GUIDE
- A PORTABLE COOLER
- ALCOHOL WIPES
- A PRACTICE PEN
- AN ACCOMPANYING SUPPORT SITE WITH EDUCATIONAL VIDEOS

SELECTED SAFETY INFORMATION (cont'd)

- ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled.
- Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms.
- ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

Please see additional Important Safety Information on page 6.

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.

If you are a Colorado prescriber, please see the Colorado WAC **disclosure form**.

If you are a Connecticut prescriber, please see the Connecticut WAC **disclosure form**.

US-VED-1979v2.0 05/24