AT A GLANCE:

THE ENTYVIO PEN

Entyvio® vedolizumab

The ENTYVIO Pen is now approved for the treatment of moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD). Below are some details you need to know regarding patients' options for their route of ENTYVIO treatment.

DOSAGES FORMS AND STRENGTHS

ENTYVIO intravenous (IV): 300 mg vedolizumab	**ENTYVIO Pen:** 108 mg vedolizumab

TRANSITIONING FROM IV INFUSIONS TO THE ENTYVIO PEN FOR SUBCUTANEOUS (SC) INJECTION[1]

Example prescriptions of ENTYVIO IV and the 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 to 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 administration for patients in clinical response or remission beyond 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 to 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 (HCP) 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 the correct SC injection technique, a patient or caregiver may inject ENTYVIO SC if an HCP determines it is appropriate. Patients and caregivers should be instructed to follow the direction for administration of ENTYVIO SC in the Instructions for Use section of the **Prescribing Information**.

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

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 the back cover.

BILLING AND CODING

The following coding information is intended as general information only.
Please refer to your patient's health plan's policies for specific billing guidance.

Product J-code[2]	
Code	**Description**
J3380	Injection, vedolizumab, intravenous, 1 mg

Current Procedural Terminology (CPT®) codes[3]	
Code	**Description**
96365	IV infusion, up to 1 hour
96413*	Chemotherapy, IV infusion

National Drug Code (NDC)[1]	
Code	**Description**
64764-300-20†	300 mg single-dose vial in individual carton
64764-108-21	108 mg single-dose prefilled pen in individual carton

ICD-10-CM codes for UC[5]	
Code	**Description**
K51.00	Ulcerative (chronic) pancolitis without complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.50	Left-sided colitis without complications
K51.80	Other ulcerative colitis without complications
K51.90	Ulcerative colitis, unspecified, without complications

ICD-10-CM codes for CD	
Code	**Description**
K50.00	Crohn's disease of small intestine without complications
K50.10	Crohn's disease of large intestine without complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.90	Crohn's disease, unspecified, without complications

*Certain Medicare contractors and private insurers do not allow the use of procedure code 96413 (chemotherapy, IV infusion, up to 1 hour) for administration of ENTYVIO. As applicable, the HCP should consult the Medicare contractor to determine which code is most appropriate, or call *EntyvioConnect* for assistance at **1-855-ENTYVIO** (1-855-368-9846).
†Proper billing may require code conversion to 11-digit format: 64764-0300-20.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on the back cover.

IMPORTANT SAFETY INFORMATION

Entyvio® vedolizumab

CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

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- **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.

References: 1. ENTYVIO (vedolizumab) prescribing information. Takeda Pharmaceuticals. **2.** HCPCS.codes. HCPCS code J3380. 2024 Healthcare Common Procedure Coding System. https://hcpcs.codes/j-codes/J3380. Accessed February 26, 2024. **3.** American Academy of Professional Coders. CPT® codes lookup. https://www.aapc.com/codes/cpt-codes-range. Accessed February 26, 2024. **4.** CMS.gov. 2024 ICD-10-CM. Centers for Medicare & Medicaid Services. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm. Accessed March 4, 2024.

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