



BILLING AND CODING

One of the most common reasons for prior authorization denial is the inclusion of an incorrect billing code. It is important to be accurate with coding for the product, administration, and associated procedures. This guide includes the most common codes to use when submitting documentation to your patient's health plan.

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

Please see Important Safety Information on [page 3](#).

BILLING AND CODING REFERENCE GUIDE

NDCs¹

ENTYVIO IV	64764-300-20*	300 mg single-dose vial in individual carton
ENTYVIO SC Pen	64764-108-21	108 mg/0.68 single-dose prefilled pen in an individual carton

Product codes² (HCPCS)

J3380	Injection, vedolizumab, intravenous, 1 mg
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Potential CPT[®] hospital outpatient procedural codes^{3,4}

96365	IV infusion, up to 1 hour
96413[†]	Chemotherapy, IV infusion up to 1 hour
96372	Therapeutic, prophylactic, or diagnostic injection; SC injection or intramuscular

Potential CPT codes for ENTYVIO SC injection education^{3‡}

98960	Education and training for patient management lasting 30 minutes
98961	Education and training for patient management for 2-4 patients lasting 30 minutes
98962	Education and training for patient management for 5-8 patients lasting 30 minutes

Diagnosis codes for ulcerative colitis (ICD-10-CM)⁵

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

Diagnosis codes (ICD-10-CM) for Crohn's disease⁵

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

*Proper billing may require code conversion to 11-digit format: 64764-0300-20.

[†]Certain Medicare contractors and private insurers do not allow the use of procedure code 96413 (chemotherapy, intravenous 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).

[‡]Medicare will not reimburse for CPT 98960, 98961, and 98962.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; HCP=healthcare provider; ICD-10-CM=International Classification of Diseases, Clinical Modification; IV=intravenous; NDC=National Drug Code; SC=subcutaneous.

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 the [next page](#).

IMPORTANT SAFETY INFORMATION (cont'd)

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 $\geq 3\%$ and $\geq 1\%$ 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 March 30, 2024. **3.** American Academy of Professional Coders. CPT codes lookup. <https://www.aapc.com/codes/cpt-codes-range>. Accessed March 30, 2024. **4.** CMS.gov. CMS-1715-F. Centers for Medicare & Medicaid Services. <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeeschedpfs-federal-regulation-notices/cms-1715-f>. Accessed March 30, 2024. **5.** CMS.gov. 2024 ICD-10-CM. Centers for Medicare & Medicaid Services. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm>. Accessed March 30, 2024.

If you are a Colorado prescriber, please see the Colorado WAC [disclosure form](#).

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