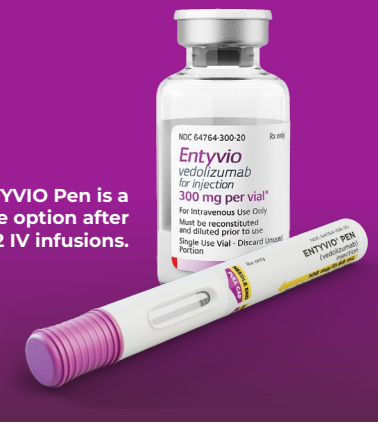
Entyvio® vedolizumab

For adults with moderately to severely active ulcerative colitis (UC) or Crohn's disease.

Updated ACG Guidelines Strongly Recommend* ENTYVIO IV

for Induction and Maintenance of Remission for Adults With Moderately to Severely Active Crohn's Disease and Ulcerative Colitis[1,2]

*Moderate quality of evidence.



The ENTYVIO Pen is a maintenance option after at least 2 IV infusions.

Please refer to the publication for a full list of recommendations from the ACG clinical guidelines for adults with ulcerative colitis and Crohn's disease.

ACG Assessment of the Strength of the Recommendation and Quality of Evidence Based on the GRADE Process[1,2]

- "Strong" recommendations are offered when desirable effects of a treatment outweigh the undesirable effects. This means that most patients should receive the recommended course of action or an alternative with similar strength of recommendation
- "Conditional" recommendations are offered when treatment benefits vs risks are uncertain or closely balanced. This means that some patients would benefit from the recommended treatment, depending on an individualized patient approach
- Quality of evidence is rated on a scale from Very Low to High based on how closely the true clinical effect aligns with the estimated effect from the evidence cited
  - *Moderate level of confidence in the estimate of effect. It is likely that the true effect is close to the estimate of the effect

Learn more about ENTYVIO ›

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 click for additional Important Safety Information.

ACG=American College of Gastroenterology; GRADE=Grading of Recommendations Assessment, Development, and Evaluation; IV=intravenous.

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Ulcerative Colitis

Select ACG Recommendations for ENTYVIO (vedolizumab)[1]

Induction of Remission in Moderately to Severely Active UC

In patients with moderately to severely active UC, the ACG recommends ENTYVIO (vedolizumab) for induction of remission (strong recommendation, moderate quality of evidence)

Maintenance of Remission in Moderately to Severely Active UC

ACG recommends continuing ENTYVIO (vedolizumab) for maintenance of remission (IV infusion or the ENTYVIO Pen) in patients with prior moderately to severely active UC now in remission after ENTYVIO induction (strong recommendation, moderate quality of evidence)

Positioning Considerations for the Patient with Moderately to Severely Active UC

In patients with moderately to severely active UC, the ACG recommends ENTYVIO (vedolizumab) as compared to Humira® (adalimumab) for maintenance of remission (strong recommendation, moderate quality of evidence)

Please refer to the publication for a full list of recommendations from the ACG clinical guidelines for adults with UC.

IMPORTANT SAFETY INFORMATION (cont.)

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 click for additional Important Safety Information.

ACG=American College of Gastroenterology; IV=intravenous; UC=ulcerative colitis.

Entyvio® vedolizumab

Crohn's Disease

Select ACG Recommendations for ENTYVIO (vedolizumab)[2]

Induction and Maintenance of Remission in Moderate to Severe Disease

ACG recommends intravenous (IV) ENTYVIO (vedolizumab) for induction and maintenance of symptomatic remission in patients with moderately to severely active Crohn's disease (strong recommendation, moderate level of evidence)

ACG recommends subcutaneous ENTYVIO (vedolizumab), the ENTYVIO Pen, as an option for maintenance of remission in patients with moderately to severely active Crohn's disease who respond to 2 intravenous (IV) induction doses of ENTYVIO (strong recommendation, moderate level of evidence)

Please refer to the publication for a full list of recommendations from the ACG clinical guidelines for adults with Crohn's disease.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS

- **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.

Please click for additional Important Safety Information.

ACG=American College of Gastroenterology.

Updated ACG Guidelines Strongly Recommend* ENTYVIO IV

for Induction and Maintenance of Remission for Adults With Moderately to Severely Active Crohn's Disease and Ulcerative Colitis[1,2]

*Moderate quality of evidence.

Please refer to the publication for a full list of recommendations.

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.
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- **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 Infusion: 300 mg vedolizumab; Subcutaneous Injection: 108 mg vedolizumab

Please click for Full Prescribing Information.

REFERENCES:

1. Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. *Am J Gastroenterol*. 2025;120(6):1187-1224. **2.** Lichtenstein GR, Loftus EV, Afzali A, et al. *Am J Gastroenterol*. 2025;120(6):1225-1264.

If you are a Colorado prescriber, please see the Colorado WAC disclosure form. If you are a Connecticut prescriber or pharmacist, please see the Connecticut WAC disclosure form.

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