ENTYVIO DOSING GUIDE

TREAT FLEXIBLY

ENTYVIO is the first and only biologic for UC with two options for maintenance therapy—intravenous (IV) infusion or subcutaneous (SC) injection[1]

For adult patients with moderately to severely active ulcerative colitis (UC) when other therapies have not worked well enough or cannot be tolerated.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

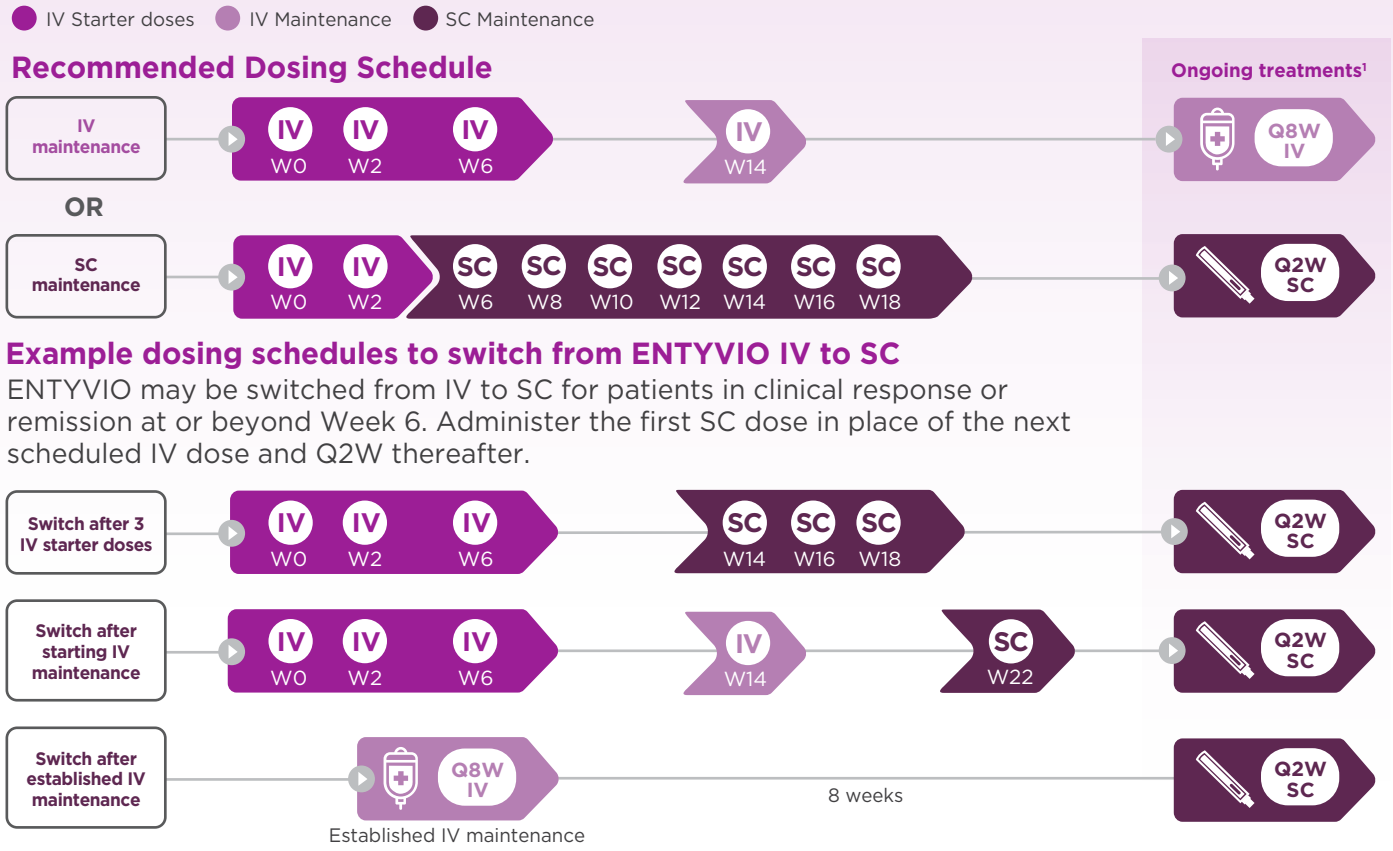
ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Please see additional Important Safety Information on last page.

Entyvio® vedolizumab | START SMART

FLEXIBILITY IN UC ADMINISTRATION OPTIONS[1]

- Recommended IV dosage: 300 mg infused by IV over approximately 30 minutes at Weeks 0, 2, and 6; then Q8W thereafter
- Following ENTYVIO IV doses at Weeks 0 and 2, ENTYVIO may be switched to SC at Week 6 with a recommended dosage of 108 mg administered Q2W
- ENTYVIO may be switched from IV to SC for patients in clinical response or remission beyond Week 6. Administer the first SC dose in place of the next scheduled IV dose and Q2W thereafter
- Discontinue ENTYVIO in patients who do not show evidence of therapeutic benefit by Week 14



Prior to administration

Patients should be brought up-to-date with all immunizations prior to starting ENTYVIO IV or SC.[1]

Concomitant therapies

ENTYVIO IV and SC can be administered concomitantly with aminosalicylates, steroids, and immunomodulators.[1]

Administration

ENTYVIO is administered as a 300 mg flat dose over an approximately 30 minute IV infusion.[1] Do not administer ENTYVIO as an IV push or bolus.[1] ENTYVIO SC is administered as a 108 mg single-dose prefilled pen.[1]

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 last page.

Entyvio® vedolizumab | START SMART

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[1]

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

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

ENTYVIO may be switched from IV to SC for patients in clinical response or remission beyond Week 6. Administer the first SC dose in place of the next scheduled IV infusion and Q2W thereafter.

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

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

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.[1] Observe patients during infusion and until the infusion is complete.[1]

Injection education

After proper training on correct subcutaneous injection technique, a patient or caregiver may administer the ENTYVIO Pen if a healthcare professional determines it is appropriate. Patients and caregivers should be instructed to follow the directions for administration of the ENTYVIO Pen in the Instructions for Use section of the Prescribing Information.[1]

For complete Dosage and Administration information, please click for Full Prescribing Information.

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

Get the latest information about ENTYVIO IV & SC at ENTYVIOHCP.com/subcutaneous-approved

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.

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.** Sandborn WJ, Baert F, Danese S, et al. Efficacy and safety of vedolizumab subcutaneous formulation in a randomized trial of patients with ulcerative colitis. *Gastroenterology.* 2020;158(3):562-572.e12.

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

US-VED-2466v1.0 09/23

Entyvio® vedolizumab | START SMART