EntyvioCONNECT | Entyvio® vedolizumab

Enrollment and Prescription Form

After the healthcare provider and the patient have considered the benefits and risks of ENTYVIO and made the decision to use ENTYVIO, *EntyvioConnect*:

Assists patients with access to ENTYVIO distribution networks and specialty pharmacies

Offers training to patients and caregivers about the safe and effective use of the product in accordance with approved labeling (e.g., instruction on self-administration, if applicable)

Offers disease state/health education to patients to facilitate patient discussions with healthcare providers

Provides education to patients about insurance coverage, e.g., education about insurance coverage and payer policies, and resources for financial assistance

Where appropriate, Patient Services may educate the prescriber or prescriber's office about insurance coverage and reimbursement for a Takeda product to facilitate the patient's access to the product, e.g., in a reimbursement model where the healthcare provider buys the product, administers the product to the patient, and seeks reimbursement for product and administration from the payer

***EntyvioConnect* offers a range of programs to help patients with access and affordability.**

ENROLL TODAY!

To enroll in *EntyvioConnect*, patients must provide information for sections 1 and 2 of the **Enrollment Form** and sign the *EntyvioConnect* **HIPAA and Patient Support Program Authorization**. Please be sure to complete and return both documents.

FAX completed forms to

1-877-488-6814

QUESTIONS? Call **1-855-ENTYVIO** (1-855-368-9846). *EntyvioConnect* Patient Support Managers are available Monday to Friday, from 8 AM to 8 PM ET (except holidays).

Please see Important Safety Information on page 8.

Takeda Patient Support

***EntyvioConnect* Enrollment and Prescription Form**
FAX pages 2, 3, 4, and 5 to 1-877-488-6814
or call **1-855-ENTYVIO** (1-855-368-9846)
Monday to Friday, from 8 AM to 8 PM ET (except holidays).

EntyvioCONNECT | Entyvio vedolizumab

1. PATIENT INFORMATION

First Name: _____ **Middle Initial:** ____ **Last Name:** _____
Home Address: _____ **City:** _____ **State:** _____ **ZIP Code:** _____
Birth Date (MM/DD/YYYY): _____ **Sex*:** ☐ **Male** ☐ **Female**
Phone: _____ **Email:** _____
Legal Representative First Name: _____ **Legal Representative Last Name:** _____
(if applicable) (if applicable)
Legal Representative Phone: _____

Is it OK to leave a detailed voice message about the status of your application, prescription, or shipments on your phone? ☐ **Yes** ☐ **No**

PLEASE NOTE: For patients receiving the ENTYVIO Pen, shipping information will be confirmed with the patient by the Specialty Pharmacy.

*Takeda and its partners recognize that patients may not identify as male or female. However, many insurance companies still require that one of these 2 fields be used for each of their members. Please indicate the sex on file with the patient's insurance company.

2. INSURANCE INFORMATION

PRIMARY INSURANCE

Plan: _____
Plan Phone: _____
Subscriber First Name: _____
Subscriber Last Name: _____
Birth Date (MM/DD/YYYY): _____
Relationship to Patient: _____
Policy ID #: _____ **Group #:** _____
PA Reference #: _____

SECONDARY INSURANCE OR PRESCRIPTION

Plan: _____
Plan Phone: _____
Subscriber First Name: _____
Subscriber Last Name: _____
Birth Date (MM/DD/YYYY): _____
Relationship to Patient: _____
Policy ID #: _____ **Group #:** _____ **OR**
RxBIN: _____ **RxPCN:** _____ **RxGroup:** _____

3. PRESCRIBER INFORMATION

Prescriber First Name: _____ **Prescriber Last Name:** _____
Practice/Facility Name: _____ **Prescriber Email:** _____
Address: _____ **City:** _____ **State:** _____ **ZIP Code:** _____
Office Contact First Name: _____ **Office Contact Last Name:** _____
Office Phone: _____ **Office Fax:** _____
Office Tax ID #: _____ **Office NPI #:** _____ **State License #:** _____ **Exp Date:** _____

PLEASE NOTE: The ENTYVIO Pen will be shipped directly to patients.
ENTYVIO IV ship-to location (select one): ☐ Prescriber office above ☐ Infusion site below

4. ENTYVIO IV INFUSION SITE INFORMATION (Must complete if different from prescriber information)

Description of infusion site of care (select one):
☐ Hospital outpatient ☐ Infusion center ☐ Nonprescribing MD's office ☐ Patient home ☐ Other

Site Provider First Name: _____ **Site Provider Last Name:** _____
Infusion Site Name: _____ **Site DEA #:** _____
Address: _____ **City:** _____ **State:** _____ **ZIP Code:** _____
Site Contact First Name: _____ **Site Contact Last Name:** _____
Site Phone: _____ **Site Fax:** _____
Site Tax ID #: _____ **Site NPI #:** _____

Patient First Name: _____ Middle Initial: ____ Last Name: _____ Birth Date: _____

5. PATIENT CLINICAL INFORMATION

Do not submit any clinical history, clinical notes, or lab result documentation to Takeda.

ICD-10-CM Diagnosis Code(s): _____

Current Medications: _____

Medication Allergies, If Any: _____

6. DOSAGE AND DIRECTIONS FOR USE (Choose ENTYVIO IV Infusion **OR** ENTYVIO Pen Injection)

ENTYVIO INTRAVENOUS (IV) INFUSION

Dose	Directions	Dispense
Initiation		
☐ Weeks 0 and 2: Infusion 300 mg IV	Infuse 1 vial IV at Weeks 0 and 2	2 vials, 0 refills
☐ Week 6: Infusion 300 mg IV	Infuse 1 vial IV at Week 6	1 vial, 0 refills
Maintenance		
☐ Infusion 300 mg IV	Infuse 1 vial IV every 8 weeks	1 vial, 6 refills
Date of last IV infusion (if applicable): _____	Date of next IV infusion: _____	

Please refer to the ENTYVIO Prescribing Information on how to reconstitute and dilute ENTYVIO IV Infusion and for the recommended Dosage and Administration of ENTYVIO IV Infusion.

If you have a patient that intends to transition to ENTYVIO SC Injection for their maintenance therapy, please complete the ENTYVIO PEN FOR SUBCUTANEOUS (SC) INJECTION table below.

PLEASE NOTE: Patient must receive 2 or more doses of ENTYVIO IV Infusion before transitioning to ENTYVIO SC Injection maintenance.

ENTYVIO PEN FOR SUBCUTANEOUS (SC) INJECTION

Dose	Directions	Dispense
If the patient has already received 2 or more doses of Entyvio IV, provide latest infusion dates below, then proceed directly to complete Maintenance section only.		
Dates of last 2 IV infusions: _____ and _____	Next IV infusion date (if applicable): _____	
Initiation		
☐ Weeks 0 and 2: Infusion 300 mg IV	Infuse 1 vial IV at Weeks 0 and 2	2 vials, 0 refills
☐ Week 6: Infusion 300 mg IV	Infuse 1 vial IV at Week 6	1 vial, 0 refills
Maintenance		
☐ Prefilled Pen 108 mg	Inject 1 pen SC every 2 weeks	2 pens, 13 refills
Date of last SC injection (if applicable): _____	Date of next SC injection: _____	

Please refer to the ENTYVIO Prescribing Information for the recommended Dosage and Administration of ENTYVIO SC Injection.

ENTYVIO Pen injections are self-administered or given by a caregiver. The patient or caregiver should be trained by a healthcare professional. *EntyvioConnect* provides free injection education either virtually or in-home to all eligible ENTYVIO patients when they opt in for Nurse Support.

PLEASE NOTE: Patient will remain on ENTYVIO IV Infusions as prescribed until ENTYVIO SC Injection coverage is secured.

☐ **Specialty Pharmacy Opt-out:** By checking this box, the prescriber requests benefit investigation only and does NOT want to triage the ENTYVIO Pen prescription to a Specialty Pharmacy. **Please skip directly to page 4 to complete the HIPAA Authorization and Support Program Enrollment pages.**

For prescribers who want to triage the ENTYVIO Pen prescription to a Specialty Pharmacy: If a specific Specialty Pharmacy is **NOT** mandated by the patient's payer, please enter the name of a preferred Specialty Pharmacy:

Specialty Pharmacy: _____

If a Specialty Pharmacy is not indicated above, an *EntyvioConnect* preferred Specialty Pharmacy will be selected for the patient.

X _____ _____

PROVIDER SIGNATURE (Dispense as written) **DATE**

By signing this form, I certify that therapy with ENTYVIO is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current ENTYVIO Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to ENTYVIO therapy to Takeda Pharmaceuticals U.S.A., Inc., including its present and future affiliates, business partners, agents and contractors, for the purpose of seeking information related to coverage and/or assisting in initiating or continuing ENTYVIO therapy. I authorize EntyvioConnect *to transmit this prescription to the appropriate pharmacy designated by me, Patient (or his/her legal representative), or Patient's plan. I agree that product provided through the Program (if applicable) shall only be used for Patient, must not be resold, offered for sale or trade, or returned for credit, nor shall Patient nor any third-party payer, Medicare, or Medicaid be charged for this product. I have read, understand, and agree to the applicable Terms and Conditions. I understand that I am under no obligation to prescribe or purchase ENTYVIO or any other product manufactured by Takeda, and I certify I have received nothing of value from Takeda or its agents or representatives for prescribing a Takeda product.*

EntyvioConnect HIPAA Authorization and Support Program Enrollment

Patient First Name: _____ Middle Initial: ____ Last Name: _____ Birth Date: _____

Patients should read the *EntyvioConnect* HIPAA Authorization and Support Program Enrollment, check the desired enrollment boxes (Text Communications and/or Nurse Support), complete the signature sections, and return both pages to *EntyvioConnect*.

NOTE: You may be able to eSign a digital version of *EntyvioConnect* HIPAA and Patient Support Program ("PSP") Authorization through the *EntyvioConnect* MyEasyConsent process. Please contact *EntyvioConnect* at 1-855-ENTYVIO (1-855-368-9846) for details.

HIPAA AUTHORIZATION

By signing the Patient Authorization section of this *EntyvioConnect* Form, I authorize my physician, health insurance, and pharmacy providers (including any Specialty Pharmacy that receives my prescription) to disclose my protected health information, including, but not limited to, information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form ("Protected Health Information"), to Takeda Pharmaceuticals U.S.A., Inc. and its present or future affiliates, including the affiliates and service providers that work on Takeda's behalf in connection with the *EntyvioConnect* Patient Support Program (the "Companies"). The Companies will use my Protected Health Information for the purpose of facilitating the provision of the *EntyvioConnect* Patient Support Program products, supplies, or services as selected by me or my physician and may include (but not be limited to) verification of insurance benefits and drug coverage, prior authorization education, financial assistance with co-pays, patient assistance programs, and other related programs. Specifically, I authorize the Companies to 1) receive, use, and disclose my Protected Health Information in order to enroll me in *EntyvioConnect* and contact me, and/or the person legally authorized to sign on my behalf, about *EntyvioConnect*; 2) provide me, and/or the person legally authorized to sign on my behalf, with educational materials, information, and services related to *EntyvioConnect*; 3) verify, investigate, and provide information about my coverage for ENTYVIO, including but not limited to communicating with my insurer, specialty pharmacies, and others involved in processing my pharmacy claims to verify my coverage; 4) coordinate prescription fulfillment; and 5) use my information to conduct internal analyses. I understand that employees of the Companies only use my Protected Health Information for the purposes described herein, to administer the *EntyvioConnect* Patient Support Program or as otherwise required or allowed under the law, unless information that specifically identifies me is removed. Further, I understand that my physician, health insurance, and pharmacy providers may receive financial remuneration from the Companies for providing Protected Health Information, which may be used for marketing purposes. I understand that Protected Health Information disclosed under this Authorization may no longer be protected by federal privacy law. I understand that I am entitled to a copy of this Authorization. I understand that I may revoke this Authorization and that instructions for doing so are contained in Takeda's Website Privacy Notice available at www.takeda.com/privacy-notice/ or I may revoke this Authorization at any time by sending written notice of revocation to *EntyvioConnect*, PO Box 2355, Morristown, NJ 07962. I understand that such revocation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire at the earliest of what is required by state law, and never in any case longer than 5 years. I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me. I also understand that if I do not sign this Authorization, I will not be able to receive *EntyvioConnect* Patient Support Program products, supplies, or services.

Please see Important Safety Information on page 8.

Patient First Name: _____ Middle Initial: ____ Last Name: _____ Birth Date: _____

SUPPORT PROGRAM ENROLLMENT

I have read and understand the applicable terms and conditions. I certify that all the information provided on this form is accurate and complete, and I agree to notify the Patient Support Program immediately if my medical or prescription drug coverage changes in any way. I understand that Takeda and its business partners will use my personal information to enroll me in the Patient Support Program, provide the support I am asking for, and offer related services to me. I authorize Takeda, its affiliates and business partners to use my personal information to provide me with information and offers related to ENTYVIO, the diseases and the conditions it treats, and related treatment options. In addition to information about ENTYVIO and related health conditions, I understand this may include information about clinical trials and market research opportunities, and other support services or programs Takeda may in the future develop for patients. I also authorize Takeda to use my de-identified information to help Takeda improve and develop products, services, materials, and programs or for health economic outcomes and market research. I understand that I may revoke my permission at any time. To learn how Takeda will use and protect my personal information, I acknowledge that I have reviewed Takeda's Privacy Notice (www.takeda.com/privacy-notice/).

TEXT COMMUNICATION ENROLLMENT

Permission for text communications: I consent to receive recurring automated text messages from the *EntyvioConnect* Patient Support Program including service updates, refill reminders and educational messages to the provided mobile number. Message and data rates may apply. Message frequency varies. Text HELP for help. Text STOP to opt out. Consent to receiving SMS messages is not a condition of purchase of goods or services. Please see the terms and conditions for text communications on page 7 and Takeda's privacy notice https://www.takeda.com/privacy-notice/.

☐ Yes, opt me in. Mobile Phone Number: _____

☐ No, I do not want to receive text alerts.

NURSE SUPPORT ENROLLMENT

Permission for Nurse Support: Yes, I would like to enroll in Nurse Support. I understand that if I elect to receive Injection Training I agree to attend in person with an *EntyvioConnect* nurse or via online, on a secure platform provided by *EntyvioConnect*.

☐ Yes, opt me in.

☐ No, I do not want to be enrolled in Nurse Support.

Patient HIPAA Authorization

I have read, understand, and agree to the release of my Protected Health Information as described above.

X _____

PATIENT SIGNATURE/LEGAL REPRESENTATIVE SIGNATURE (indicate relationship) **DATE**

Patient Support Program Enrollment

I have read, understand, and agree to the use of my personal information for the purposes as described above.

X _____

PATIENT SIGNATURE/LEGAL REPRESENTATIVE SIGNATURE (indicate relationship) **DATE**

Please see Important Safety Information on page 8.

EntyvioConnect Terms and Conditions

START PROGRAM

The Start Program provides ENTYVIO at no cost to eligible new-to-therapy patients who are excluded from coverage, received a denial of coverage, and/or received a prior authorization denial from their commercial payer. Patients eligible for federal or state healthcare programs (Medicare, Medicaid, TRICARE, etc.) are ineligible. Patients who experience a Plan Exclusion due to Alternate Funding Program (AFP) involvement are not eligible for the Start Program. Patients must have a valid prescription for ENTYVIO. The Start Program provides ENTYVIO at no cost to eligible patients for up to three years. Patients must submit evidence of denied coverage, excluded from coverage, or prior authorization denial from their commercial payer and other required documents. There is no purchase obligation by virtue of a patient's participation in the Start Program. Free product provided through the Start Program is only available through the Start Program's contracted non-commercial Specialty Pharmacy. No claim for reimbursement for product dispensed through the Start Program may be submitted to any third-party payer. Benefits provided under the Start Program are not transferable. The Start Program is a one-time offer per patient. Eligibility will be determined on a case-by-case basis. Takeda reserves the right to change or end the Start Program at any time, and other terms and conditions may apply.

BRIDGE PROGRAM

The Bridge Program provides continuity of care when an eligible ENTYVIO patient experiences a loss of or gap in commercial insurance coverage or authorization. The Bridge Program provides up to 6 months of product at no cost to enrolled patients while they obtain commercial coverage for ENTYVIO. Patients must be currently receiving ENTYVIO therapy and experiencing a gap in or loss of commercial coverage. The Bridge Program is not available to patients who are eligible for federal or state healthcare programs (Medicare, Medicaid, TRICARE, etc.). Patients who experience a Plan Exclusion due to Alternate Funding Program (AFP) involvement are not eligible for the Bridge Program. Patients who have not yet received their first dose of ENTYVIO are not eligible. There is no purchase obligation by virtue of a patient's participation in the Bridge Program. Free product provided through the Bridge Program is only available through the Bridge Program's contracted non-commercial Specialty Pharmacy. No claim for reimbursement for product dispensed through the Bridge Program may be submitted to any third-party payer. Benefits provided under the Bridge Program are not transferable. Eligibility will be determined on a case-by-case basis. Takeda reserves the right to change or end the Bridge Program at any time, and other terms and conditions may apply.

CO-PAY PROGRAM

The *EntyvioConnect* Co-Pay Program ("Co-Pay Program") provides financial support for commercially insured patients who qualify for the Co-Pay Program. Participation in the Co-Pay Program and provision of financial support is subject to all Co-Pay Program terms and conditions, including but not limited to eligibility requirements, the maximum benefit per claim, and the Maximum Annual Benefit. By enrolling in the Co-Pay Program, you agree that the program is intended solely for the benefit of you—not health plans and/or their partners. Further, you agree to comply with all applicable requirements of your health plan. The Co-Pay Program cannot be used if the patient is a beneficiary of, or any part of the prescription is covered by: 1) any federal, state, or government-funded healthcare program (Medicare, Medicare Advantage, Medicaid, TRICARE, etc.), including a state pharmaceutical assistance program (the Federal Employees Health Benefit (FEHB) Program is not a government-funded healthcare program for the purpose of this offer), 2) the Medicare Prescription Drug Program (Part D), or if the patient is currently in the coverage gap, or 3) insurance that is paying the entire cost of the prescription. Takeda reserves the right to change or end the Co-Pay Program at any time without notice, and other terms and conditions may apply. If you have enrolled in an accumulator adjustment, co-pay maximizer, or similar program that purports to help manage costs, or later learn that your insurance company or health plan has implemented such a program, you agree to inform *EntyvioConnect* at 1-844-368-9846. In an accumulator adjustment program, payments made by you that are subsidized by a manufacturer co-pay assistance program do not count toward your deductibles and other out-of-pocket cost-sharing obligations. In a co-pay maximizer program, the amount of your out-of-pocket cost obligation is increased to match support offered by a manufacturer co-pay assistance program. It may be possible that you are unaware whether you are subject to these programs when you enroll in the Co-Pay Program. Takeda will monitor program utilization data and reserves the right to discontinue assistance under the Co-Pay Program at any time if Takeda determines that you are subject to a co-pay maximizer, accumulator, or similar program. The Maximum Annual Benefit under the Co-Pay Program is subject to change without notice. Subject to all terms and conditions, the Maximum Annual Benefit under the Co-Pay Program may be applied to out-of-pocket cost for your ENTYVIO prescription, including co-pay, co-insurance or deductible. The Co-Pay Program is for medication costs only and does not include costs to give you your treatment. Subject to all terms and conditions, the Maximum Annual Benefit under the Co-Pay Program is $20,000 per calendar year. However, except where prohibited by law, if your insurance company or health plan implements a co-pay maximizer program or similar program, you will have a reduced Maximum Annual Benefit of $9,000 per calendar year. If your insurance company or health plan removes ENTYVIO from such program, subject to all terms and conditions, you will be eligible for co-pay assistance up to the Maximum Annual Benefit for patients who are not subject to maximizer adjustment or similar programs. The actual application and use of the benefit available under the co-pay assistance program may vary on a per-claim, monthly, quarterly, and/or annual basis, depending on each individual patient's health plan and other prescription drug costs. Patient may not seek reimbursement from any other plan or program (Flexible Spending Account [FSA], Health Savings Account [HSA], Health Reimbursement Account [HRA], etc.) for any out-of-pocket costs covered by the Co-Pay Program. Patient or healthcare provider may be required to

continued

CO-PAY PROGRAM (continued)

submit an Explanation of Benefits (EOB) following each infusion to the Co-Pay Program. The Co-Pay Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your insurance provider or health plan. If your health plan changes you must notify *EntyvioConnect* at 1-844-368-9846. This offer is not transferable and is limited to one offer per person and may not be combined with any other coupon, discount, prescription savings card, rebate, free trial, patient assistance, co-pay maximizer, alternative funding program, co-pay accumulator, or other offer, including those from third parties and companies that help insurers or health plans manage costs. Not valid if reproduced. By utilizing the Co-Pay Program, you hereby accept and agree to abide by these terms and conditions. Any individual or entity who enrolls or assists in the enrollment of a patient in the Co-Pay Program represents that the patient meets the eligibility criteria and other requirements described herein. You must meet the program eligibility requirements every time you use the program.

TEXT COMMUNICATIONS

EntyvioConnect Patient Support Program text messages are recurring automated program messages, which may include service updates, refill reminders and educational messages. By agreeing to these *EntyvioConnect* (the "Program") text message terms and conditions, you agree to receive text messages on your mobile device subject to the Terms & Conditions described below. You also consent to receive autodialed and/or pre-recorded calls and/or text messages from or on behalf of the Program at the telephone number provided above. You understand that this consent is not a condition of purchase or use of the Program or of any Takeda product or service. You can unsubscribe from receiving text messages by texting STOP. You will remain enrolled in the *EntyvioConnect* Patient Support Program. For questions about this Program, text HELP or contact the customer support center at 1-855-ENTYVIO. Message frequency varies. Such messages may be nonmarketing messages related to the Patient Support Program. Message and data rates may apply. You represent that you are the account holder for the mobile telephone number(s) that you provide to opt into the Program. You are responsible for notifying Takeda immediately if you change your mobile telephone number. You may notify Takeda of a number change by calling 1-855-ENTYVIO. Data obtained from you in connection with your registration for, and use of, this SMS service may include your phone number and/or email address, related carrier information, and elements of pharmacy claim information and will be used to administer this Program and to provide Program benefits such as information about your prescription, refill reminders, as well as Program updates and alerts. We are able to deliver on most of the major and minor carriers: i.e., Verizon, Sprint, AT&T, T-Mobile and MetroPCS. If you are unsure whether your carrier supports short codes, please contact your wireless provider directly. Carriers are not liable for delayed or undelivered messages. Please visit Takeda's Privacy Notice https://www.takeda.com/privacy-notice/ or contact us for additional information.

VIDEO EDUCATION

Patients participating in virtual injection education agree to attend via an online, secure platform provided by *EntyvioConnect*.

Please see Important Safety Information on page 8.

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
- 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 or pharmacist, please see the Connecticut WAC disclosure form.

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