EntyvioConnect

ENROLLMENT FORM

For your patients prescribed Entyvio, *EntyvioConnect* gives access to the following programs:

Benefits Investigation

Support during the process of determining a patient's insurance benefits and eligibility for certain *EntyvioConnect* services

Prior Authorization (PA) Support

Assistance in obtaining PA approval from the patient's insurance company to cover Entyvio

Denial and Appeal Support

Guidance to support an office when appealing any denied PA requests

Co-Pay Program

Allows commercially insured, eligible patients to pay as little as $5 per dose*, up to a total benefit of $20,000 per year

Start Program

New-to-Entyvio patients who have received a denied PA from a commercial health plan are eligible to receive Entyvio at no cost for up to 1 year while the appeals process is conducted

Bridge Program

Entyvio patients with a temporary loss or gap in commercial coverage or authorization are eligible to receive Entyvio at no cost for up to 6 months

Nurse Support

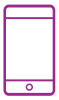
Enrolled patients will be paired with a Nurse Educator to receive continued guidance throughout their treatment on Entyvio. Our nurses do not provide medical advice. Patients can request Nurse Support when they sign up on page 4

See pages 5 and 6 for terms and conditions for *EntyvioConnect* and its programs and services.

ENROLL TODAY!

To enroll in *EntyvioConnect*, have your patients fill out the first and second pages of the enrollment form, ensuring they sign both gray boxes.

FAX completed forms to
1-877-488-6814



Call 1-855-ENTYVIO
(1-855-368-9846)
with any questions

EntyvioConnect Patient Support Managers are available Monday to Friday from 8 am to 8 pm ET (except holidays).

EntyvioCONNECT | Entyvio® vedolizumab

Please see Indications and Important Safety Information on page 7.

*The *EntyvioConnect* Co-Pay Program ("Co-Pay Program") provides financial support for commercially insured patients who qualify for the Co-Pay Program. The Co-Pay Program cannot be used if 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 patient is currently in the coverage gap, or 3) insurance that is paying the entire cost of the prescription. 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 submit an Explanation of Benefits (EOB) following each infusion to the Co-Pay Program. Takeda reserves the right to change or end the Co-Pay Program at any time without notice, and other terms and conditions may apply. Offer not valid for patients under 18 years of age. Assistance under the Co-Pay Program is not transferable. 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. If your insurance situation 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, or other offer. Not valid if reproduced.

DIAGNOSIS CODES

This guide is designed to support the reimbursement process for both providers and payers by providing coding information for Entyvio. Providers are responsible for determining and submitting the appropriate codes, charges, and modifiers for all medically appropriate services and products. Please contact individual payers for current and specific coding, coverage, and payment policies.

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

The following ICD-10-CM diagnosis codes may be appropriate to describe these disease states:

ICD-10-CM codes for ulcerative colitis[1]

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 Crohn's disease[1]

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

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

EntyvioConnect Enrollment and Prescription Form

FAX page 3 and page 4 to 1-877-488-6814
or call **1-855-ENTYVIO** (1-855-368-9846)
Monday through Friday, from 8 am to 8 pm ET (except holidays)

EntyvioCONNECT | Entyvio® vedolizumab

1. PATIENT INFORMATION (COMPLETE AND SUBMIT PATIENT AUTHORIZATIONS ON PAGE 4)

Name (First, Middle Initial, Last) _____ Birth Date (MM/DD/YYYY) _____ Gender ☐ Male ☐ Female
Address _____ Email _____ Primary Phone _____
City/State/ZIP _____
Legal Representative Name (if applicable) _____ Legal Representative Primary Phone (if applicable) _____

2. PATIENT INSURANCE INFORMATION (FAX A COPY OF BOTH SIDES OF THE PRIMARY AND/OR SECONDARY INSURANCE CARD[S])

Primary Insurance Plan _____ Plan Phone _____
Subscriber Name _____
Birth Date _____ Relationship to Patient _____
Policy ID # _____ Group # _____
PA Reference # _____

Secondary or Prescription Plan _____ Plan Phone _____
Subscriber Name _____
Birth Date _____ Relationship to Patient _____
Policy ID # _____ Group # _____ **OR**
RxBIN _____ RxPCN _____ RxGroup _____

3. PRESCRIBER INFORMATION

Prescriber Name (First, Last) _____ Preferred Contact Name _____
Practice/Facility Name _____ Office Phone _____ Office Fax _____
Address _____ Co-pay/Claims/AR Fax (if different from above) _____
City/State/ZIP _____ Tax ID # _____ NPI # _____

4. INFUSION SITE INFORMATION (REQUIRED IF DIFFERENT FROM PRESCRIBER)

Treatment Provider Name (First, Last) _____
Practice/Facility Name _____
Address _____
City/State/ZIP _____

Description of site of care for infusion
☐ Hospital outpatient ☐ Infusion center ☐ Non-prescribing MD's office ☐ Patient home ☐ Other

Office Phone _____ Office Fax _____
Tax ID # _____ NPI # _____
Preferred Contact Name _____

5. PATIENT CLINICAL INFORMATION AND PRIOR THERAPIES

ICD-10-CM Diagnosis Code(s) _____
Current Medications _____

Prior therapies[2]: ☐ Humira® (adalimumab) ☐ 6-MP/azathioprine ☐ Cimzia® (certolizumab pegol) ☐ Remicade® (infliximab) ☐ Corticosteroids ☐ Stelara® (ustekinumab)
☐ Other _____

Medication Allergies, if any _____

6. DOSAGE AND DIRECTIONS FOR USE (REQUIRED FOR SPECIALTY PHARMACY TRIAGE)

Please complete Entyvio prescription information. Attach your prescription if this form does not comply with state laws (NY and NJ).

ENTYVIO IV PRESCRIPTION INFORMATION (COMPLETE THIS SECTION)

Dose	Dispense	Description
Initiation		
☐ **Week 0: Infusion 300 mg IV**	1 vial	**14-day supply; 1 prescription, no refill**
☐ **Week 2: Infusion 300 mg IV**	1 vial	**30-day supply; 1 prescription, no refill**
☐ **Week 6: Infusion 300 mg IV**	1 vial	**60-day supply; 1 prescription, no refill**
Maintenance		
☐ **Infusion 300 mg IV**	1 vial	**60-day supply; 1 prescription, 6 refills**

Please refer to the Entyvio Prescribing Information on how to reconstitute and dilute Entyvio for intravenous (IV) infusion.

Do you intend to buy and bill? ☐ Yes ☐ No

PRESCRIBER SIGNATURE

X _____ **X** _____

PRESCRIBER SIGNATURE (Dispense as written) **DATE** **PRESCRIBER SIGNATURE (Substitution permitted)** **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.*

Please see Indications and Important Safety Information on page 7.
For complete Dosage and Administration, please see full Prescribing Information, including Medication Guide.

7. PATIENT INFORMATION AND AUTHORIZATION

Name (First, Middle Initial, Last) _____ Birth Date (MM/DD/YYYY) _____ Gender ☐ Male ☐ Female

Email _____ Okay to leave a message about the status of my enrollment or prescription? ☐ Yes ☐ No

Mobile Phone _____ Alternate Phone _____

8. PATIENT HIPAA AUTHORIZATION

By signing the Patient Authorization section on the second page of this *EntyvioConnect* Enrollment 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 healthcare provider may receive financial remuneration from Takeda Pharmaceuticals U.S.A. for marketing services. 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 cancel this Authorization and that instructions for doing so are contained in Takeda's Website Privacy Notice available at www.takeda.com/privacy-notice/. I understand that such cancellation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from the date it is signed and provided on the first page of this enrollment form, unless a shorter period is provided for by state law. 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.

Patient 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 described on page 5, section 9.

x _____

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

☐ Check this box if you wish to opt-in for *EntyvioConnect* Nurse Support

☐ Check this box if you wish to enroll in text message communication, as described on page 6, section 14

9. PATIENT SUPPORT PROGRAM ENROLLMENT

Enroll me in the *EntyvioConnect* Patient Support Program (the "Program"). 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 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 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/).

10. PATIENT HIPAA AUTHORIZATION

By signing the Patient Authorization section on the second page of this *EntyvioConnect* Enrollment 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 healthcare provider may receive financial remuneration from Takeda Pharmaceuticals U.S.A. for marketing services. 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 cancel this Authorization and that instructions for doing so are contained in Takeda's Website Privacy Notice available at www.takeda.com/privacy-notice/. I understand that such cancellation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from the date it is signed and provided on the first page of this enrollment form, unless a shorter period is provided for by state law. 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.

11. START PROGRAM TERMS AND CONDITIONS

The Start Program provides Entyvio at no cost to eligible new-to-therapy patients who have received a prior authorization denial from their commercial payer. Patients eligible for federal or state healthcare programs (Medicare, Medicaid, TRICARE, etc.) are ineligible. Patients must have a valid prescription for Entyvio that is consistent with Entyvio's label. The Start Program provides Entyvio at no cost to eligible patients for up to one year. If a patient enrolled in the Start Program is still appealing coverage at one year, the patient may be eligible for additional Entyvio under the Start Program. Patients must submit evidence of 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.

12. BRIDGE PROGRAM TERMS AND CONDITIONS

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 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. The Bridge 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 Bridge Program at any time, and other terms and conditions may apply.

13. CO-PAY PROGRAM TERMS AND CONDITIONS

The *EntyvioConnect* Co-Pay Program ("Co-Pay Program") provides financial support for commercially insured patients who qualify for the Co-Pay Program. The Co-Pay Program cannot be used if 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 patient is currently in the coverage gap, or 3) insurance that is paying the entire cost of the prescription. 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 submit an Explanation of Benefits (EOB) following each infusion to the Co-Pay Program. Takeda reserves the right to change or end the Co-Pay Program at any time without notice, and other terms and conditions may apply. Offer not valid for patients under 18 years of age. Assistance under the Co-Pay Program is not transferable. 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. If your insurance situation 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, or other offer. Not valid if reproduced.

14. TEXT MESSAGING

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.

Participants will receive an average of 5 text messages each month while enrolled in the Program. Such messages may be nonmarketing messages related to the Patient Support Program.

There is no fee payable to Takeda to receive text messages; however, your carrier's 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.

Takeda will not be liable for any delays in the receipt of any SMS messages as delivery is subject to effective transmission from your network operator.

This Program is valid with most major US carriers, including Verizon Wireless, Sprint, Nextel, Boost Mobile, T-Mobile®, AT&T, Alltel, ACS Wireless, Bluegrass Cellular, Carolina West Wireless, CellCom, Cellular One of East Central Illinois (ECIT), Cincinnati Bell, Cricket, C-Spire Wireless, Duet IP (AKA Max/Benton/Albany), Element Mobile, Epic Touch, GCI Communications, Golden State, Hawkeye (Chat Mobility), Hawkeye (NW Missouri Cellular), Illinois Valley Cellular (IVC), Inland Cellular, iWireless, Keystone Wireless (Immix/PC Management), MetroPCS, MobiPCS, Mosaic, MTPCS/Cellular One (Cellone Nation), Nex-Tech Wireless, nTelos, Panhandle Telecommunications, Pioneer, Plateau, Revol Wireless, Rina-Custer, Rina-All West, Rina-Cambridge Telecom Coop, Rina-Eagle Valley Comm, Rina-Farmers Mutual Telephone Co, Rina-Nucla Nutria Telephone Co, Rina-Silver Star, Rina-South Central Comm, Rina-Syringa, Rina-UBET, Rina-Manti, Simmetry, South Canaan/CellularOne of NEPA, Thumb Cellular, Union Wireless, United Wireless, U.S. Cellular, Viaero Wireless, Virgin Mobile, and West Central Wireless (includes Five Star Wireless).

Takeda may be required to contact the user if an adverse event is reported.

You agree to indemnify Takeda and any third parties texting on its behalf in full for all claims, expenses, and damages related to or caused, in whole or in part, by your failure to immediately notify us if you change your telephone number, including but not limited to all claims, expenses, and damages related to or arising under the Telephone Consumer Protection Act.

Takeda reserves the right to rescind, revoke, or amend the Program without notice at any time.

You can unsubscribe from this Program by texting STOP. For questions about this Program, text HELP or contact the customer support center at 1-855-ENTYVIO.

For appropriate adult patients with moderate to severe ulcerative colitis or Crohn's disease when other therapies have not worked well enough or cannot be tolerated.

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.
- 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.
- 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), 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 is caused by the John Cunningham (JC) virus and typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported in the post marketing setting (e.g., human immunodeficiency virus [HIV] infection with a CD4 count of 300 cells/mm^3 and prior and concomitant immunosuppression). Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and 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 a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- 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.
- 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.
- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please see full Prescribing Information, including Medication Guide.

INDICATIONS

Adult Ulcerative Colitis

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active UC.

Adult Crohn's Disease

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active CD.

References: 1. Centers for Medicare & Medicaid Services. 2022 ICD-10-CM. Accessed September 7, 2021. https://www.cms.gov/medicare/icd-10/2022-icd-10-cm.
2. Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals.

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