EntyvioCONNECT | Entyvio vedolizumab

EntyvioConnect Enrollment Form

For your patients prescribed ENTYVIO, *EntyvioConnect* gives access to the following programs and services:

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

***EntyvioConnect* Co-Pay Program**
Allows commercially insured, eligible patients to pay as little as $5 per dose up to the maximum annual program benefit. Please read the full terms and conditions for the Co-Pay Program on page 7

Start Program*
New-to-ENTYVIO patients with commercial health insurance whose PA has been denied are eligible to receive ENTYVIO intravenous (IV) infusions at no cost for up to 1 year while the appeals process is conducted

Available for IV infusions only

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

Available for IV infusions or subcutaneous (SC) injections

Nurse Support
Patients can opt in (on page 6) to be paired with a Nurse Educator and receive guidance throughout their treatment on ENTYVIO. SC injection education for patients with ulcerative colitis (UC) for the ENTYVIO Pen can also be provided either virtually or in-home when applicable. Our nurses do not provide medical advice

Text Updates
Patients can opt in (on page 6) to get important updates via text directly from *EntyvioConnect*

ENROLL TODAY!

To enroll in *EntyvioConnect*, patients must provide information for sections 1 and 2 of the enrollment form and sign the Patient HIPAA Authorization and Patient Support Program Enrollment gray boxes on page 6. Please be sure to complete sections 3, 4, 5, and 6.

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).

***Additional eligibility requirements may apply.**

See pages 6, 7, and 8 for terms and conditions for *EntyvioConnect* and its programs and services.

Please see Important Safety Information on page 8.

Takeda Patient Support

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 International Classification of Diseases, Tenth Revision, Clinical Modification (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

Please see Important Safety Information on page 8.

EntyvioConnect Enrollment and Prescription Form

FAX pages 3, 4, 5, and 6 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:** _____
Legal Representative Name (if applicable): _____
Legal Representative Primary Phone: _____
Email: _____

PLEASE NOTE: For UC patients receiving the ENTYVIO Pen, shipping information will be confirmed with the patient by the specialty pharmacy.

Preferred form of contact (select one): ○ Phone ○ Text ○ Email

Birth Date (MM/DD/YYYY): _____
Sex*: ○ Male ○ Female
Primary Phone: _____ ○ Mobile ○ Home ○ Office
Other Phone: _____ ○ Mobile ○ Home ○ Office

Is it OK to leave a detailed voice message about the status of your application, prescription, or shipments on your phone? **Check all that apply:**

☐ Primary Phone ☐ Other Phone

Preferred time (select one): ○ Morning ○ Day ○ Evening

*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. PATIENT INSURANCE INFORMATION

What type of health insurance do you have? Check all that apply.

☐ A plan through my employer ☐ A plan I purchased on my own ☐ Medicare Advantage ☐ TRICARE (military benefit) ☐ None
☐ A Marketplace plan ☐ Medicare ☐ Medicaid ☐ Other

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

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

3. PROVIDER INFORMATION

Provider First Name: _____
Provider Last Name: _____
Practice/Facility Name: _____
Address: _____
City: _____ **State:** _____ **Zip Code:** _____

PLEASE NOTE: The ENTYVIO Pen will be shipped directly to patients.

ENTYVIO IV ship to location (select one): ○ Provider office above ○ Infusion site below

Provider Email: _____
Preferred Contact Name: _____
Office Phone: _____ **Office Fax:** _____
Tax ID #: _____
NPI #: _____
State License #: _____ **Exp Date:** _____

4. ENTYVIO IV INFUSION SITE INFORMATION (MUST COMPLETE IF DIFFERENT FROM PROVIDER INFORMATION)

Description of infusion site of care (select one):

○ Hospital outpatient ○ Infusion center ○ Nonprescribing MD's office ○ Patient home ○ Other

Treatment Provider First Name: _____
Treatment Provider Last Name: _____
Practice/Facility Name: _____
Address: _____
City: _____ **State:** _____ **Zip Code:** _____

Preferred Contact Name: _____
Office Phone: _____ **Office Fax:** _____
Tax ID #: _____
NPI #: _____
Facility DEA: _____

5. PATIENT CLINICAL INFORMATION

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: _____

PATIENT

First Name: _____ **Middle Initial:** _____

Last Name: _____ **DOB:** _____

6. DOSAGE AND DIRECTIONS FOR USE (CHOOSE ENTYVIO IV OR THE ENTYVIO PEN)

Please review options below and only fill out one of the tables (either IV or the ENTYVIO Pen prescription; filling out both could delay fulfillment and/or treatment). Attach your prescription if this form does not comply with state laws (NY and NJ). NOTE: In certain circumstances this prescription may need to be validated and/or verified.

ENTYVIO INTRAVENOUS (IV) INFUSION

Dose	Directions	Dispense
Initiation		
☐ Week 0: Infusion 300 mg IV	14-day supply; 1 prescription, no refill	1 vial
☐ Week 2: Infusion 300 mg IV	30-day supply; 1 prescription, no refill	1 vial
☐ Week 6: Infusion 300 mg IV	60-day supply; 1 prescription, no refill	1 vial
Maintenance		
☐ Infusion 300 mg IV	60-day supply; 1 prescription, 6 refills	1 vial
Date of last IV infusion (if applicable): _____ and date of next IV infusion: _____		

Do you intend to buy and bill ENTYVIO IV doses?

◯ Yes ◯ No

Please refer to the ENTYVIO Prescribing Information on how to reconstitute and dilute ENTYVIO for Infusion.

All new ENTYVIO patients start treatment with at least 2 IV initiation doses. If you have a patient with UC who hopes to transition to the ENTYVIO Pen for their maintenance therapy, please submit a new *EntyvioConnect* enrollment form for SC once they have completed at least 2 doses of IV.

ENTYVIO PEN FOR SUBCUTANEOUS (SC) INJECTION

Dose	Directions	Dispense
If the patient has received 2 or more doses of ENTYVIO IV, please provide the following:		
Dates of last 2 IV infusions: _____ and _____ ; next IV infusion date (if applicable): _____		
Maintenance		
☐ Prefilled Pen 108 mg	Inject 1 pen SC every 2 weeks	2 pens, 13 refills
Date of last SC injection (if applicable): _____ and date of next SC injection: _____		

Please note: Patient will remain on ENTYVIO IV Infusions as prescribed until ENTYVIO Pen coverage is secured.

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

ENTYVIO SC formulation is available for patients with moderate to severe UC. 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**.

If a specific Specialty Pharmacy is NOT mandated by the patient's payer, please identify if you or the patient has a preferred Specialty Pharmacy:

_____

NOTE: If none is identified by you or the patient, 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.

PATIENT

First Name: _____ **Middle Initial:** _____

Last Name: _____ **DOB:** _____

7. PATIENT 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 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 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 13185, La Jolla, CA 92039-3185. 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 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
First Name: _____ **Middle Initial:** _____
Last Name: _____ **DOB:** _____

8. PATIENT 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/).

9. TEXT MESSAGE COMMUNICATIONS

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.

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 U.S. 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 (Immis/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 Start Wireless). 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.

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.

Patient HIPAA Authorization

I have read, understand, and agree to the release of my protected health information as described on page 5, section 7.

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 on page 6, section 8.

☐ **Check this box if you wish to opt in to enroll in Nurse Support**

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

Text Communication Enrollment

I have read, understand, and agree to opt in for text communications as described on page 6, section 9.

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

10. VIDEO EDUCATION

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

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. 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. 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 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

Please see Important Safety Information on page 8.

13. CO-PAY PROGRAM TERMS AND CONDITIONS (cont'd)

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 plan 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.

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 Infusion: 300 mg vedolizumab; 108 mg Subcutaneous Injection

Please click for Full Prescribing Information.

References: 1. CMS.gov. 2023 ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm. Accessed June 26, 2023. **2.** Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals.

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

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Takeda Patient Support

Takeda