EntyvioCONNECT | Entyvio® vedolizumab

PATIENT SUPPORT THROUGHOUT THE ENTIRE INSURANCE PROCESS

Learn how to enroll your patients in *EntyvioConnect* and access its full range of programs and services

Takeda Patient Support

Please see Important Safety Information on page 10.

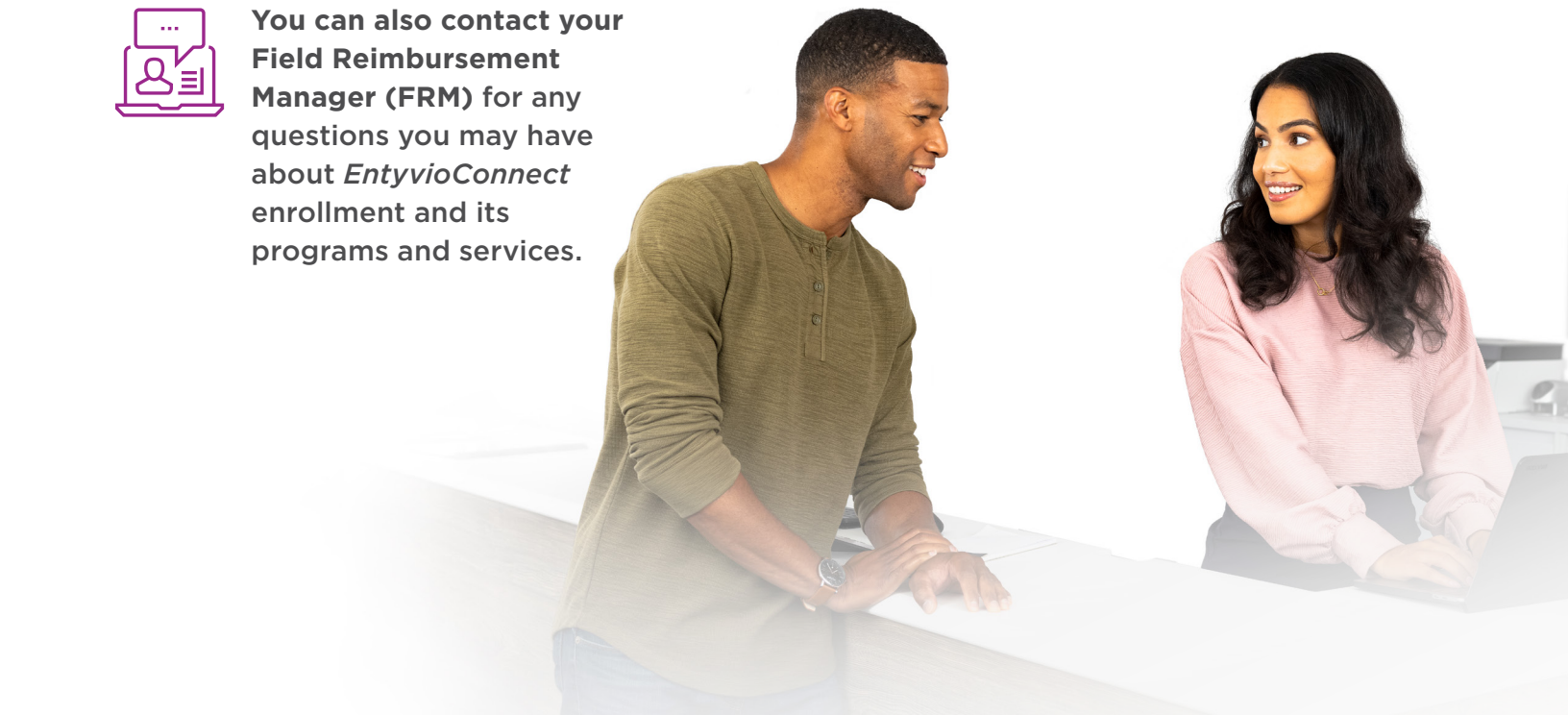
EntyvioCONNECT | Entyvio vedolizumab

EACH PATIENT'S CIRCUMSTANCES VARY WHILE LIVING WITH A CHRONIC DISEASE

EntyvioConnect offers a range of programs tailored to help patients in the way they need it most after the prescribing decision has been made. Use this enrollment guide for step-by-step instructions on how to get them set up.

Contact us with any questions
Connect with a Case Manager at **1-855-ENTYVIO (1-855-368-9846)**, Monday to Friday, from 8 AM to 8 PM ET (except holidays) or visit **EntyvioHCP.com/Access-Support**.

You can also contact your Field Reimbursement Manager (FRM) for any questions you may have about *EntyvioConnect* enrollment and its programs and services.



Takeda Patient Support

EntyvioCONNECT | Entyvio vedolizumab

SUPPORT THROUGHOUT THE TREATMENT JOURNEY

After you've prescribed ENTYVIO, you can help **connect patients with all that *EntyvioConnect* has to offer**.

INSURANCE SUPPORT

Benefits investigation (BI)

Prior authorization (PA) assistance

Appeals and denials assistance

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 9**.

NURSE SUPPORT

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

FOR PATIENTS WITH A DENIED PA

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.

FOR PATIENTS WITH A LAPSE IN COVERAGE

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 SC injections.

TEXT UPDATES

Patients can opt in to get important updates via text directly from *EntyvioConnect*.

*Additional eligibility requirements may apply.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see additional Important Safety Information on page 10.

Takeda Patient Support

EntyvioCONNECT | Entyvio vedolizumab

PATIENT ENROLLMENT INSTRUCTIONS

EntyvioConnect HCP Portal

The easiest and quickest way to sign your patients up for *EntyvioConnect* is directly in the online portal at **EntyvioConnectportal.com**. If you do not have an account yet, ask your FRM to help you get set up.

By Fax

You and your patient can also complete the ***EntyvioConnect* Enrollment Form** together at your office and then fax it to: **1-877-488-6814**.

You and your patient will need to fill out the following sections of the application:

SECTION	
1	**PATIENT INFORMATION** • Patient fills out personal information and contact details • Patient can check box for leaving a message about enrollment or prescription status **NOTE:** For patients receiving the ENTYVIO Pen, shipping information will be confirmed by the specialty pharmacy and the product will be shipped directly to the patient.
2	**PATIENT INSURANCE INFORMATION** • This is necessary to perform a BI and to see if the patient is eligible for the *EntyvioConnect* Co-Pay Program • Be sure to obtain copies of both sides of the patient's insurance card(s)
3	**PROVIDER INFORMATION** • Include your tax identification (ID) and National Provider Identifier numbers
4	**ENTYVIO IV INFUSION SITE INFORMATION** • Must be completed if different from provider information

HCP=healthcare provider.

Please see Important Safety Information on page 10.

Takeda Patient Support

PATIENT ENROLLMENT INSTRUCTIONS (cont'd)

EntyvioCONNECT | Entyvio vedolizumab

SECTION

5

PATIENT CLINICAL INFORMATION

- Include International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis code(s) and prior therapies. Please see **page 8** for commonly used ICD-10-CM diagnosis codes

6

DOSAGE AND DIRECTIONS FOR USE

- Choose only **one**: ENTYVIO IV or the ENTYVIO Pen
- Complete the ENTYVIO prescription information for your patient
- Remember to check the box if you intend to buy and bill IV doses
- Sign on the line to confirm prescription decision:
  - Dispense as written
  - Substitution permitted
- ENTYVIO patients must start treatment with at least 2 IV initiation doses. For patients ready to transition to SC injections for their maintenance therapy, please submit a **new** *EntyvioConnect* Enrollment Form and fill out the SC prescription section

PATIENT HIPAA AUTHORIZATION, PATIENT SUPPORT PROGRAM ENROLLMENT, TEXT MESSAGE COMMUNICATIONS, AND NURSE SUPPORT ENROLLMENT

- After reading the *EntyvioConnect* HIPAA Authorization and Support Program Enrollment information, your patient must sign the Patient HIPAA Authorization box at the bottom of page 5 to authorize the release of personal and health information for compliance with the Health Insurance Portability and Accountability Act (HIPAA) and to officially enroll in *EntyvioConnect*
- After reading the Support Program Enrollment information, your patient must sign the Patient Support Program Enrollment box at the bottom of page 5 to authorize the use of their personal information for enrollment in *EntyvioConnect* support programs
- Patients must opt in for Nurse Support by checking the box
- Text communication enrollment is optional. Patients must check "Yes" and provide their phone number to opt in

Please see Important Safety Information on page 10.

Takeda Patient Support

EntyvioCONNECT | Entyvio vedolizumab

FOR PATIENTS WHO WANT TO ENROLL ON THEIR OWN

Co-Pay Program and Nurse Support

If your patient wants to enroll in either of these *EntyvioConnect* programs on their own, they can sign up at **Entyvio.com/Register**.

Your patient will need to fill out the following sections of the application:

SECTION	
1	**CURRENT TREATMENT** • Diagnosis • Select if patient is new or currently taking ENTYVIO
2	**SERVICE SELECTION** • Co-Pay Program and insurance help • Nurse Support • Text message treatment reminders
3	**PATIENT CONTACT INFORMATION**

Please see Important Safety Information on page 10.

Takeda Patient Support

FOR PATIENTS WHO WANT TO ENROLL ON THEIR OWN (cont'd)

EntyvioCONNECT | Entyvio vedolizumab

SECTION

4

PROVIDER INFORMATION

5

CONSENT AND HIPAA AUTHORIZATION

- Patient's digital signature is required

Once all sections are filled out, your patient is signed up.

Print an on-demand membership ID card

If your patients are eligible for the Co-Pay Program, they will receive a confirmation with a membership ID card that they can download.

If your patients are **not eligible for the Co-Pay Program**, someone from *EntyvioConnect* will reach out based on their specified communication preference.

If your patients have questions about this, they can contact **1-844-ENTYVIO (1-844-368-9846)**.

Please see Important Safety Information on page 10.

Takeda Patient Support

INFORMATION ON **CODING**

Health plan administrative processes rely heavily on codes for decision-making. One of the most common reasons for a PA denial is incorrect coding. The following coding information is intended as general information only. Please refer to your patient's insurance policies for specific billing guidance.

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

Please see additional Important Safety Information on page 10.

EntyvioConnect 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 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.

Please see Important Safety Information on page 10.

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
- ENTYVIO Subcutaneous (SC) Injection: 108 mg vedolizumab

Please click for Full Prescribing Information.

Reference: 1. CMS.gov. 2024 ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services. https://www.cms.gov/medicare/icd-10/2024-icd-10-cm. Accessed May 14, 2024.

Takeda Patient Support

Takeda