

EntyvioCONNECT



ACCESS AND AFFORDABILITY ARE OUR PRIORITY

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



Please see Indications and Important Safety Information on **page 9**.

THERE IS A PROGRAM FOR YOUR ENTYVIO PATIENT, REGARDLESS OF THEIR CIRCUMSTANCE

This *EntyvioConnect* Enrollment Guide provides an overview of our programs and services and step-by-step enrollment instructions, whether you chose to enroll a patient through the *EntyvioConnect* portal, by fax, or online. Refer to this enrollment guide if you have any questions regarding the information needed to complete the enrollment form.



Contact us with any questions

Connect with a Patient Support 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**](https://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.



OUR PROGRAMS AND SERVICES

EntyvioConnect offers your patients support throughout the entire insurance approval process.



INSURANCE SUPPORT

Benefits investigation

Prior authorization (PA) assistance

Appeals and denials assistance



CO-PAY ASSISTANCE

Co-Pay Program: Eligible patients may pay as little as \$5 per dose*



ONE-ON-ONE NURSE SUPPORT

Nurse Educators: Enrolled patients get one-on-one guidance, resources, and support to get started and stay on treatment. Our nurses do not provide medical advice



FOR PATIENTS WITH A DENIED PA

Start Program: Provides Entyvio at no cost for up to 1 year while appeals process is conducted

Eligibility

- Available to new-to-Entyvio patients only
 - Denial must have been from a commercial health plan
 - Evidence of appeal activity must be sent to *EntyvioConnect* throughout the year
- Additional eligibility requirements may apply.



FOR PATIENTS WITH A LAPSE IN COVERAGE

Bridge Program: Provides Entyvio at no cost for up to 6 months if patient experiences a temporary loss or gap in coverage (eg, job loss, insurance transition)

Eligibility

- Patient must have been on Entyvio prior to coverage loss
 - Entyvio coverage was from a commercial health plan
- Additional eligibility requirements may apply.

*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.

Please see Indications and Important Safety Information on [page 9](#).

FOR ACCESS TO ALL OF OUR PROGRAMS



Enroll by fax
Complete the enrollment form and fax it to:
1-877-488-6814.



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

SECTION

1

PATIENT INFORMATION

2

PATIENT INSURANCE INFORMATION

- This is necessary to perform a benefits investigation and to see if the patient is eligible for the Co-Pay Program
- Be sure to obtain copies of both sides of the patient's insurance card(s)

3

PRESCRIBER INFORMATION

- Include your tax ID # and NPI #

4

INFUSION SITE INFORMATION

FOR ACCESS TO ALL OF OUR PROGRAMS (cont'd)

SECTION

5

PATIENT CLINICAL INFORMATION AND PRIOR THERAPIES

- Include ICD-10-CM diagnosis code(s) and prior therapies.
Please see **page 8** for relevant ICD-10-CM diagnosis codes

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DOSAGE AND DIRECTIONS FOR USE

- Complete the Entyvio prescription information for your patient
- Remember to check the box if you intend to buy and bill
- Sign on the line to confirm prescription decision:
 - Dispense as written
 - Substitution permitted

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PATIENT INFORMATION AND AUTHORIZATION

- Patient fills out personal information and contact details
- Patient can check box for leaving a message about enrollment or prescription status

8

PATIENT HIPAA AUTHORIZATION

- Patient must sign both gray boxes to authorize the release of personal and health information for compliance with HIPAA and to officially enroll in *EntyvioConnect*
- Patient can opt in for Nurse Support and/or to receive text message communication



Download an ***EntyvioConnect*** enrollment form.

FOR ACCESS TO THE **CO-PAY PROGRAM** **AND NURSE EDUCATORS ONLY**



Enroll online

If your patient wants to enroll in *EntyvioConnect* on their own, direct them to [**Entyvio.com/Register**](https://Entyvio.com/Register) to complete enrollment.



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

SECTION

1

CURRENT TREATMENT

2

SERVICE SELECTION

- ☐ Co-Pay Program and insurance help
- ☐ Nurse Educator
- ☐ Text message treatment reminders

3

PATIENT CONTACT INFORMATION

FOR ACCESS TO THE CO-PAY PROGRAM AND NURSE EDUCATORS ONLY (cont'd)

SECTION

4

PRESCRIBER INFORMATION

5

CONSENT AND HIPAA AUTHORIZATION

- Patient's digital signature is required



Once all sections are filled out, your patients are **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 membership ID card**, they will receive a message regarding their ineligibility. Advise your patients to contact **1-855-ENTYVIO (1-855-368-9846)** to discuss their co-pay eligibility.

INFORMATION ON CODING

EntyvioCONNECT

Entyvio[®]
vedolizumab

Your office is responsible for determining and submitting the appropriate codes, charges, and modifiers for all medically appropriate services and products. The health plan administrative process relies heavily on the use of these codes, and their accuracy is critical to preventing a delay in the approval process. To help avoid any delays, we have included relevant ICD-10-CM diagnosis codes to help you complete the *EntyvioConnect* enrollment form.

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 colitis¹

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 disease¹

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

For adult patients with moderate to severe ulcerative colitis and Crohn's disease when other treatments 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/mm³ 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 $\geq 3\%$ and $\geq 1\%$ 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 (UC)

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

Adult Crohn's Disease (CD)

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

Reference: 1. Centers for Medicare & Medicaid Services. 2022 ICD-10-CM. Accessed March 8, 2022. <https://www.cms.gov/medicare/icd-10/2022-icd-10-cm>

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