

EntyvioCONNECT

 **Entyvio**<sup>®</sup>  
vedolizumab

**HERE TO HELP YOUR  
ENTYVIO PATIENTS GET  
AHEAD FROM THE START**



Please see selected Important Safety Information throughout and Indications and Full Important Safety Information on [page 10](#).



Patient and healthcare provider portrayals.

# OUR PROGRAMS AND SERVICES

EntyvioCONNECT

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Once ENTYVIO has been prescribed to your patient, *EntyvioConnect* programs and services are available to support them throughout the entire insurance approval process.

## EntyvioConnect

Patients must be enrolled in **EntyvioConnect** to have access to these programs and services. All programs and services have separate eligibility requirements.



### INSURANCE SUPPORT

- Benefits investigation
- Prior authorization (PA) assistance
- Appeals and denials assistance

For patients with a denied PA:

- **Start Program** (available for intravenous [IV] infusions only)

For patients with a lapse in coverage:

- **Bridge Program** (available for IV infusions or subcutaneous [SC] injections)



### FINANCIAL ASSISTANCE

For commercially insured patients:

- **EntyvioConnect Co-Pay Program**

For patients who are underinsured or rendered uninsured:

- **Patient Assistance Program**



### NURSE SUPPORT

- **Patients who opt in are paired with a Nurse Educator who is available to:**
  - Follow up with the patient at regular intervals during treatment
  - Provide general information on ENTYVIO and practical tips for living with their condition
  - Help set treatment, health, and lifestyle goals to discuss with their doctor
  - Provide ENTYVIO Pen injection education either virtually or in-home when applicable
  - Our nurses do not provide medical advice

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## Field Reimbursement Manager (FRM)

If you have questions about insurance support, co-pay assistance, or Nurse Support for ENTYVIO, your FRM or Patient Support Manager are available to help.



### HEALTH PLAN EXPERTISE

- Knowledge of the local market and geography
- Previously defined requirements for core payers
- Medical benefit design and implementation
- Distinction between pharmacy vs buy-and-bill or site of care
- Step-edit legislation and external review



### PATIENT ACCESS

- Assist in the entire insurance approval process, from benefits investigations to billing
- Educate office staff on best practices to potentially reduce time for patient access to treatment
- Available for site-of-care assistance



### REIMBURSEMENT CYCLE MANAGEMENT

- Billing and coding
- PA denials and appeals
- Best practices for accurate PA submissions



Relevant *EntyvioConnect* enrollment forms, claims forms, and sample health plan letters are available for download at [EntyvioHCP.com/Access-Support](https://EntyvioHCP.com/Access-Support).



## Insurance Support

### SCENARIO

### HOW WE CAN HELP

**My patient just got a very large bill for ENTYVIO treatment. The health plan was supposed to pay for it.**

- *EntyvioConnect* can follow up with the health plan to investigate the root of the miscommunication

**I'd like to start a patient on ENTYVIO. How can I verify insurance coverage?**

- An *EntyvioConnect* Patient Support Manager will do a benefits investigation (BI) on your patient's behalf and send you a summary of coverage
- If a BI is requested for patients with ulcerative colitis (UC), a Patient Support Manager can inquire about coverage for both IV infusion and the ENTYVIO Pen for SC injection

**My patient's health plan requires a PA for ENTYVIO.**

- Since ENTYVIO IV is an infusion, it will most likely be covered under the medical benefit. A PA should be submitted under the medical benefit prior to the first infusion date or if a previous PA is about to expire
- The ENTYVIO Pen is covered under the pharmacy benefit since it is self-administered. Start the PA process 2-4 weeks before the next scheduled infusion date
- Contact your FRM with any questions you may have about ENTYVIO PA

**I verified a patient's benefits, but now the health plan is denying the claim.**

- A Patient Support Manager can help identify the reason for denial; it may be as simple as an error on the PA
- If you still don't understand the reason for denial, contact an FRM for assistance

### INDICATIONS

For adult patients with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD) when other therapies have not worked well enough or cannot be tolerated.

### 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.

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## Insurance Support

**I need to find a specialty pharmacy (SP) for my UC patient prescribed the ENTYVIO Pen.**

- Your FRM can provide you with a list of our current distribution network of SPs. Be sure to cross-check the SPs on the list against the ones that are covered by your patient's health plan
- Once coverage is confirmed, you can complete any required PAs and send the SP an electronic prescription for the ENTYVIO Pen

**The health plan denied a PA for ENTYVIO.**

- Either an FRM or a Patient Support Manager can help identify the reason for denial and educate you on the appeals process
- The **Start Program\*** is for new-to-ENTYVIO patients who have been denied a PA from a commercial health plan. ENTYVIO IV may be provided at no cost for up to 1 year while the appeals process is conducted
  - Evidence of appeal activity must be sent to **EntyvioConnect** throughout the year
  - Available for IV infusions only

**My patient is starting a new job, and the new employer won't cover ENTYVIO for the first 60 days.**

- The **Bridge Program\*** is available for ENTYVIO patients with a temporary loss or gap in commercial coverage or authorization (eg, job loss, insurance transition). ENTYVIO is provided at no cost for up to 6 months
  - After 6 months, **EntyvioConnect** will look for available coverage assistance programs, if needed
  - Available for IV or ENTYVIO Pen for SC injections

### SELECTED SAFETY INFORMATION

- If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled.
- Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms.
- ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

\*Additional eligibility requirements may apply.

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## Financial Assistance

### SCENARIO

**My patient can't afford ENTYVIO treatment.**

**Primary insurance only covers part of the cost of ENTYVIO.**

**I have a patient with Medicare but no secondary insurance.**

**My patient won't be able to continue ENTYVIO due to financial concerns.**

### HOW WE CAN HELP

- Regardless of your patient's insurance type, *EntyvioConnect* has different solutions that may be able to support your patient
  - **If your patient has commercial insurance:** the **Co-Pay Program** may lower an eligible patient's out-of-pocket costs to 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](#)
  - **If your patient has government insurance, is underinsured, or rendered uninsured:** a Patient Support Manager can research financial assistance options to help with out-of-pocket costs, including the Patient Assistance Program for those who meet income and eligibility criteria



## Nurse Support

### SCENARIO

**My patient is new to ENTYVIO and has questions about treatment and how to manage their condition.**

**My patient needs ENTYVIO but lives hours away from a clinic or infusion center.**

### HOW WE CAN HELP

- During *EntyvioConnect* enrollment, a patient can opt in to be paired one-on-one with a Nurse Educator and receive guidance throughout their treatment on ENTYVIO
  - Injection education with the ENTYVIO Pen can also be provided either virtually or in-home when applicable
  - For patients who are eligible for the ENTYVIO Pen, call *EntyvioConnect* to request a free kit for your patient that includes a training guide, practice pen, alcohol wipes, and a portable cooler
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- An FRM can search for site-of-care assistance options for your patient
  - Use the ENTYVIO Infusion Center Locator to find infusion services based on your patient's needs



## EntyvioConnect Enrollment

### SCENARIO

**I would like my patients prescribed ENTYVIO to have access to patient support.**

**My patient is already enrolled in *EntyvioConnect*, but has been prescribed the ENTYVIO Pen.**

### HOW WE CAN HELP

- The easiest and quickest way to sign your patients up for *EntyvioConnect* is directly in the online portal at [EntyvioConnectportal.com](https://EntyvioConnectportal.com). If you do not have an account yet, ask your FRM to help you get set up
- You and your patient can also complete the enrollment form together at your office and then fax it to: 1-877-488-6814
- If your patient is only interested in the Co-Pay Program or Nurse Support, they can sign up on their own at [Entyvio.com/Register](https://Entyvio.com/Register)
- When your UC patient is ready to transition to the ENTYVIO Pen, you are required to submit a new *EntyvioConnect* enrollment form and select the SC prescription
  - This step is required so we can identify SPs in our current network and to ensure SC patients have access to additional resources relevant to their new way of receiving treatment

### SELECTED SAFETY INFORMATION

- If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled.
- Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms.
- ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

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## 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 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  $\geq 3\%$  and  $\geq 1\%$  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 (IV) Infusion: 300 mg vedolizumab
- ENTYVIO Subcutaneous (SC) Injection: 108 mg vedolizumab

#### Please click for [Full Prescribing Information](#).

If you are a Colorado prescriber, please see the Colorado WAC [disclosure form](#).