EntyvioCONNECT | Entyvio® vedolizumab

FROM PRESCRIPTION TO **PATIENT SUPPORT**

Programs and services available to your ENTYVIO patients

START →

Please see additional Important Safety Information on pages 29-30.

Hypothetical HCP portrayal

THEIR TREATMENT STARTS WITH YOU

You know what's best for your patients. So when you're ready to treat, we're here to help you avoid roadblocks to care. That way, you can get the information and support you need when navigating a patient's coverage.

Takeda Patient Support

Please see additional Important Safety Information on pages 29-30.

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SUPPORT FOR YOUR OFFICE

Inside this toolkit:

1 **Treatment Options**
- ENTYVIO intravenous (IV) infusions
- ENTYVIO Pen for subcutaneous (SC) injection

2 ***EntyvioConnect***
- Support programs
- Enrollment
- Portal

3 **Benefits Road Map**
- Getting started: medical vs pharmacy benefit
- Benefit investigation (BI)
- Prior authorization (PA)
- Denials
- Appeals

4 **Getting ENTYVIO to Your Patients**
- IV prescription ordering
- SC prescription ordering
- IV treatment administration
- SC treatment

5 **Claims and Reimbursement**
- Claims forms
- Electronic data interchange (EDI) and electronic funds transfer (EFT)

6 **Important Safety Information**

Look for this symbol throughout the presentation for clickable links to helpful resources.

Please see additional Important Safety Information on pages 29-30.

Hypothetical HCP and patient portrayals

1 TREATMENT OPTIONS
2 ENTYVIOCONNECT
3 BENEFITS ROAD MAP
4 GETTING ENTYVIO TO YOUR PATIENTS
5 CLAIMS AND REIMBURSEMENT
6 IMPORTANT SAFETY INFORMATION

1 TREATMENT OPTIONS

> ENTYVIO IV infusions are available for adult patients with moderately to severely active (UC) and Crohn's disease (CD)

> The ENTYVIO Pen for SC injection is available for maintenance in adult patients with moderately to severely active UC

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 pages 29-30.

ENTYVIO® (vedolizumab)

EntyvioCONNECT | Entyvio vedolizumab

GENERIC NAME: Vedolizumab

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:

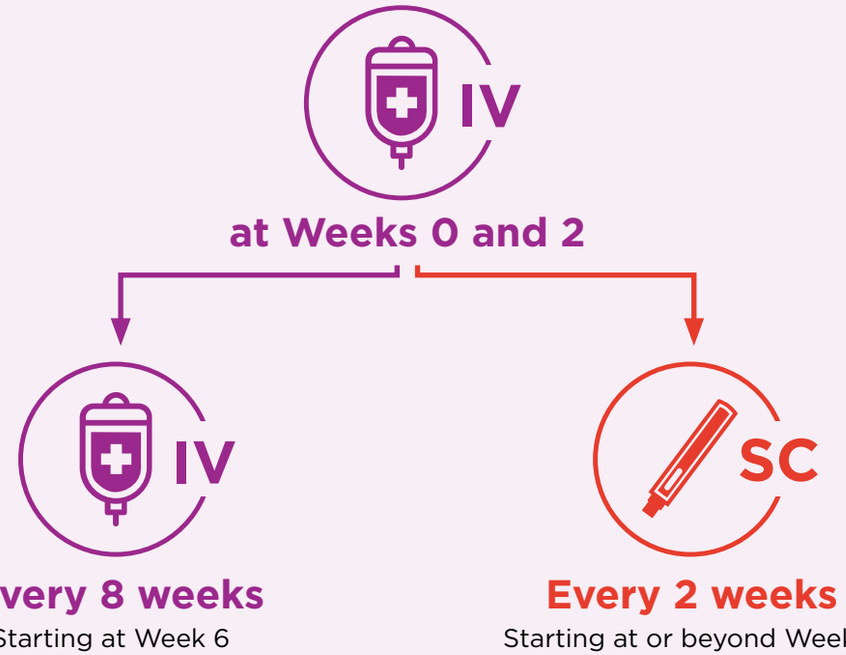
- ENTYVIO (IV) Injection: 300 mg vedolizumab
- ENTYVIO Pen for SC injection (UC only): 108 mg vedolizumab

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.

Adult patients with moderately to severely active UC now have 2 maintenance options for their ENTYVIO treatment.

All patients start on ENTYVIO IV infusions



For complete dosing and administration information, please see Full Prescribing Information.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

EntyvioCONNECT | Entyvio vedolizumab

2 ENTYVIOCONNECT

Because each patient's circumstances vary, *EntyvioConnect* offers a range of programs to help patients in the way they need it most.

> Support throughout the treatment journey
> Enrolling patients
> *EntyvioConnect* healthcare provider (HCP) portal

Please see additional Important Safety Information on pages 29-30.

SUPPORT THROUGHOUT THE TREATMENT JOURNEY

EntyvioCONNECT | Entyvio vedolizumab

After your patient has been prescribed ENTYVIO, you can help **connect them with all that *EntyvioConnect* has to offer.**

INSURANCE SUPPORT

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

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 IV infusions at no cost for up to 1 year while the appeals process is conducted. Available for IV infusions only.

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 28**.

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 self-administered SC injections.

NURSE SUPPORT

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

*Additional terms and conditions may apply.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

TWO WAYS TO ENROLL PATIENTS

Getting patients signed up to take advantage of *EntyvioConnect* resources is easy.

EntyvioConnect 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 Field Reimbursement Manager (FRM) to help you get set up.

By Fax

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

Co-Pay Program and Nurse Support

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

ENTYVIOCONNECT RESOURCE

The ***EntyvioConnect* Enrollment Guide** provides the information you and your staff need to enroll patients into *EntyvioConnect* programs.

Please see additional Important Safety Information on pages 29-30.

THE *ENTYVIOCONNECT* PORTAL

EntyvioCONNECT | Entyvio vedolizumab

Use the portal to enroll patients in *EntyvioConnect*, track their case status, and manage documentation for *EntyvioConnect* services.

Manage these services through the portal:

- BI
- PA support
- Denial and appeal support
- Co-Pay Program enrollment
- Patient Assistance Program (PAP)
- Start Program
- Bridge Program
- Nurse support

If you need help with the portal, please call *EntyvioConnect* at **1-855-ENTYVIO (1-855-368-9846)**, Monday to Friday, from 8 AM to 8 PM ET (except holidays).

PORTAL RESOURCES

FAQ

Provider User Guide

Quick Start Guide

Please see additional Important Safety Information on pages 29-30.

1 TREATMENT OPTIONS
2 ENTYVIOCONNECT
3 BENEFITS ROAD MAP
4 GETTING ENTYVIO TO YOUR PATIENTS
5 CLAIMS AND REIMBURSEMENT
6 IMPORTANT SAFETY INFORMATION

3 BENEFITS ROAD MAP

Getting a prescription approved by health plans can be time-consuming. Use this section to help you navigate the different coverage scenarios you might run into along the way.

> Before you begin: Medical vs pharmacy benefit
> Benefit investigation
> Prior authorization
> PA process: ENTYVIO IV vs SC
> Denials
> Coding guide
> Appeals

Please see additional Important Safety Information on pages 29-30.

BEFORE YOU BEGIN: MEDICAL VS PHARMACY BENEFIT

EntyvioCONNECT | Entyvio vedolizumab

Depending on the treatment, **a drug usually falls under the medical or pharmacy benefit.***

	MEDICAL	PHARMACY
Route of administration	ENTYVIO IV infusions	ENTYVIO Pen for SC injection
Who dispenses the drug?	HCP, infusion center, home infusion, hospital outpatient	Specialty pharmacy (SP)
Coverage requirements	Medical policy	Formulary
Patient out-of-pocket (OOP) considerations	Co-pay and coinsurance; could be one for drug and one for administration depending on the patient's coverage	Co-pay or coinsurance for drug
Coding category	Healthcare Common Procedure Coding System (HCPCS)/J-Code	National Drug Code (NDC)

Infusion treatments like ENTYVIO IV are typically covered by a patient's medical benefit.

Self-administered SC injections like the ENTYVIO Pen are typically covered by a patient's pharmacy benefit.

*Some health plans cover IV infusions under the pharmacy benefit or self-administered SC injections under the medical benefit, but this is not typical.

Reference: Vogenberg FR, Santilli J, Eng K. Bend the curve: a new era for the management of specialty pharmaceuticals. Access Market Intelligence. 2016. https://accessmarketintell.com/wp-content/uploads/2016/08/Bend-the-curve-final.pdf. Accessed July 12, 2023.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

BENEFIT INVESTIGATION

EntyvioCONNECT | Entyvio vedolizumab

To get started, contact *EntyvioConnect* or reach out directly to your patient's health plan over the phone or online to understand the specific coverage criteria and requirements for ENTYVIO.

CONSIDERATIONS FOR APPROVAL

- **What is the route of administration?**
- **Where is the drug being administered?**
- **Is the drug covered under the medical or pharmacy benefit?**

When you submit a BI for UC patients, inquire about coverage for both IV and SC treatments.* That way, you'll be prepared if they want to switch later.

Patients who are new to ENTYVIO: If the health plan covers ENTYVIO IV on the medical benefit and the ENTYVIO Pen on the pharmacy benefit, then separate benefits verifications will need to be completed by the health plan and pharmacy benefit manager (PBM).

Patients currently receiving ENTYVIO IV: Check to see what, if any, restrictions are in place for the ENTYVIO Pen. They may vary from those for IV treatment.

COVERAGE RESOURCE

EntyvioConnect offers a sample **Benefits Investigation Form** to educate office staff on how to review and interpret verification results.

*Separate prescriptions need to be written for IV and SC formulations.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

PRIOR AUTHORIZATION

Health plans typically require you to demonstrate on a PA form that **their specific requirements for ENTYVIO have been met.**

Considerations when submitting a PA for ENTYVIO:

- ✓ Know how the health plan prefers to receive submissions
- ✓ Know what forms and documentation are required
- ✓ Review the health plan's coverage policy to understand the PA requirements
- ✓ Ensure you have the results for any required lab work

Possible PA and step therapy requirements for ENTYVIO

For UC or CD

Inadequate response with, lost response to, or were intolerant to a tumor necrosis factor blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids

COVERAGE RESOURCE

The **ENTYVIO PA Checklist** can help you understand the necessary requirements and processes involved when submitting a PA request to a patient's health plan.

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.

Reference: Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals.

Please see additional Important Safety Information on pages 29-30.

PA TIMING FOR ENTYVIO IV AND ENTYVIO PEN FOR UC PATIENTS

Initiation doses
Start the medical benefit PA process after the prescribing decision has been made

IV maintenance
Submit a new medical benefit PA if there is an expiration date for the initial submission

ENTYVIO Pen maintenance
Start the PA process **2-4 weeks before** the next scheduled infusion date

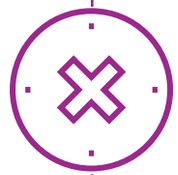
For details on navigating the PA process and the ENTYVIO Pen prescription and administration, see section 4, **Getting ENTYVIO to your patients**.

Please see additional Important Safety Information on pages 29-30.

DENIALS

Common reasons for a denial include:

- Missing or inaccurate information
- Not covered by medical policy
- Step-edit required
- Infusion center/site of care is not preferred
- Billed to the incorrect benefit (medical vs pharmacy)
- **Incorrect diagnosis code**



One of the most common reasons for a PA denial is incorrect coding.

Health plan administrative processes rely heavily on codes for decision-making.

Note: For UC patients who are waiting to transition from IV infusions to the ENTYVIO Pen, a PA may be denied if they have not yet completed at least 2 IV initiation doses.

Please see additional Important Safety Information on pages 29-30.

CODING REFERENCE GUIDE

EntyvioCONNECT | Entyvio® vedolizumab

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

NDC for ENTYVIO[1]	
Code	**Description**
64764-300-20*	300 mg single-dose vial in individual carton
64764-108-21	108 mg single-dose prefilled pen in individual carton

Product J-code[2]	
Code	**Description**
J3380	Injection, vedolizumab, 1 mg

Potential Current Procedural Terminology (CPT®) hospital outpatient procedural codes[3,4]	
Code	**Description**
96365	IV Infusion, up to 1 hour
96413†	Chemotherapy, IV Infusion, up to 1 hour
96372	Therapeutic, prophylactic, or diagnostic injection, SC injection or intramuscular

Potential CPT codes for ENTYVIO SC injection education	
Code	**Description**
98960‡	Education and training for patient management lasting 30 minutes
98961‡	Education and training for patient management for 2-4 patients lasting 30 minutes
98962‡	Education and training for patient management for up to 8 patients lasting 30 minutes

*Proper billing may require code conversion to 11-digit format: 64764-0300-20.

†Certain Medicare contractors and private insurers do not allow the use of procedure code 96413 (chemotherapy, intravenous [IV] infusion, up to 1 hour) for administration of ENTYVIO. As applicable, the HCP should consult the Medicare contractor to determine which code is most appropriate, or call *EntyvioConnect* for assistance at **1-855-ENTYVIO (1-855-368-9846)**.

‡Medicare will not reimburse for CPT 98960, 98961, and 98962.

References: 1. Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals. **2.** HCPCS.codes. HCPCS code J3380. 2023 Healthcare Common Procedure Coding System. https://hcpcs.codes/j-codes/J3380. Accessed July 10, 2023. **3.** American Academy of Professional Coders. CPT codes lookup. https://www.aapc.com/codes/cpt-codes-range. Accessed July 10, 2023. **4.** CMS.gov. CMS-1715-F. U.S. Centers for Medicare & Medicaid Services. https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1751-f. Accessed August 8, 2023.

Please see additional Important Safety Information on pages 29-30.

CODING REFERENCE GUIDE (cont'd)

ICD-10-CM codes for ulcerative colitis	
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	
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

These are some examples of possible ICD-10-CM codes. Certain payers may require other codes not listed here. Please reach out to your FRM to discuss further.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **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.

Reference: CMS.gov. 2023 ICD-10-CM. Centers for Medicare & Medicaid Services. Accessed June 26, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm.

Please see additional Important Safety Information on pages 29-30.

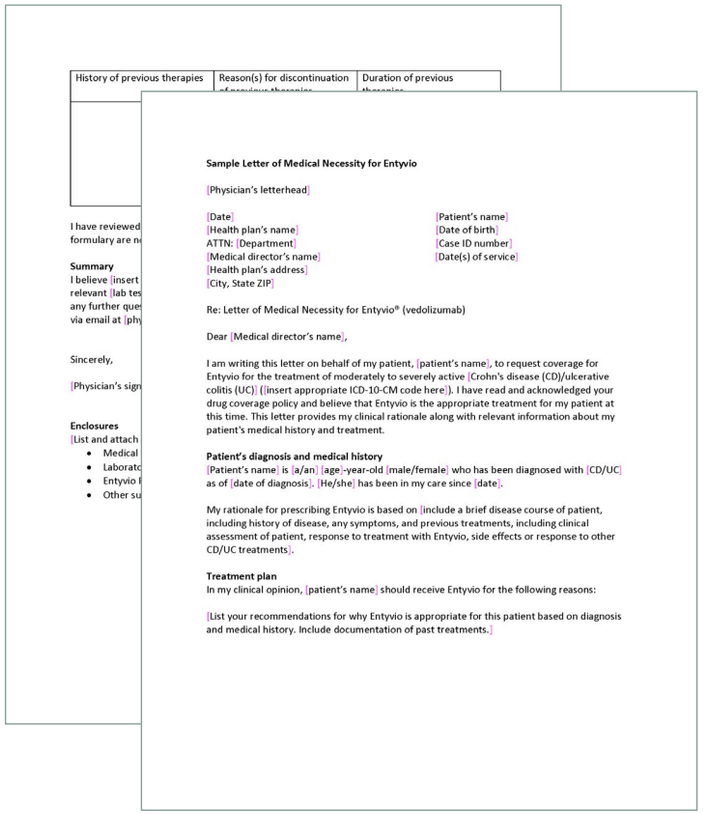
APPEALS

If your patient is denied coverage and you appeal the decision, you're required to **explain your rationale for prescribing ENTYVIO in a Letter of Appeal**.

If the first PA appeal is denied:

- Contact the health plan and ask for a supervisor or manager to explain the next level of appeal and what information is required
- Request a peer-to-peer review with a medical director at the health plan
- Follow up if you do not hear from the health plan

Sample Letters of Appeal



History of previous therapies | Reason(s) for discontinuation | Duration of previous

I have reviewed
formulary are n

Summary
I believe [insert
relevant [lab tes
any further ques
via email at [phy

Sincerely,

[Physician's sign

Enclosures
[List and attach
- Medical
- Laborato
- Entyvio
- Other su

Sample Letter of Medical Necessity for Entyvio

[Physician's letterhead]

[Date]
[Health plan's name]
ATTN: [Department]
[Medical director's name]
[Health plan's address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Case ID number]
[Date(s) of service]

Re: Letter of Medical Necessity for Entyvio® (vedolizumab)

Dear [Medical director's name],

I am writing this letter on behalf of my patient, [patient's name], to request coverage for Entyvio for the treatment of moderately to severely active [Crohn's disease (CD)/ulcerative colitis (UC)] ([insert appropriate ICD-10-CM code here]). I have read and acknowledged your drug coverage policy and believe that Entyvio is the appropriate treatment for my patient at this time. This letter provides my clinical rationale along with relevant information about my patient's medical history and treatment.

Patient's diagnosis and medical history
[Patient's name], is [a/an] [age]-year-old [male/female] who has been diagnosed with [CD/UC] as of [date of diagnosis]. [He/she] has been in my care since [date].

My rationale for prescribing Entyvio is based on [include a brief disease course of patient, including history of disease, any symptoms, and previous treatments, including clinical assessment of patient, response to treatment with Entyvio, side effects or response to other CD/UC treatments].

Treatment plan
In my clinical opinion, [patient's name] should receive Entyvio for the following reasons:

[List your recommendations for why Entyvio is appropriate for this patient based on diagnosis and medical history. Include documentation of past treatments.]

APPEALS AND DENIALS RESOURCES

The **ENTYVIO Appeals and Denials Checklist** can help you understand the process of appealing a denied PA and lists any pertinent information that you may need.

Sample letter of medical necessity

Sample letter of appeal due to coding error

Sample letter of appeal due to rejected claim

Please see additional Important Safety Information on pages 29-30.

1 TREATMENT OPTIONS
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4 GETTING ENTYVIO TO YOUR PATIENTS

Once your patient is adequately covered for ENTYVIO, it's time to determine the best route of acquiring, administering, and billing for their treatment.

> Prescribing ENTYVIO
> Ordering ENTYVIO IV and the ENTYVIO Pen
> Administering ENTYVIO IV or the ENTYVIO Pen

Please see additional Important Safety Information on pages 29-30.

HOW TO PRESCRIBE ENTYVIO

EntyvioCONNECT | Entyvio vedolizumab

Example Prescriptions of ENTYVIO IV and ENTYVIO Pen

START

Start with 300 mg IV infusions for:

Weeks 0 and 2

Rx: ENTYVIO 300 mg IV
Sig: 1 IV infusion Q2W
Disp: 2 IV doses
Refills: 0

For IV doses, submit a medical benefit prior authorization (PA) 2-4 weeks before first infusion date.

MAINTAIN

Starting at Week 6, continue with infusions every 8 weeks

Rx: ENTYVIO 300 mg IV
Sig: 1 IV infusion Q8W
Disp: 1 IV dose
Refills:

ENTYVIO may be switched from IV to SC for patients in clinical response or remission beyond Week 6.

Starting at Week 6, begin ENTYVIO SC 108 mg and continue every 2 weeks

For patients who have received 2 or more IV doses, administer the first SC dose in place of the next scheduled IV infusion.

Rx: ENTYVIO Pen 108 mg*
Sig: 1 single-dose prefilled pen Q2W
Disp: 2 SC pens
Refills:

To transition UC patients to ENTYVIO SC, start the pharmacy benefit PA process 2-4 weeks before the next scheduled infusion date.

Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.

Monitoring

ENTYVIO IV should be administered by a healthcare professional prepared to manage hypersensitivity reactions, including anaphylaxis, if they occur. Appropriate monitoring and medical support measures should be available for immediate use. Observe patients during infusion and until the infusion is complete.

Injection education

After proper training on correct SC injection technique, a patient or caregiver may inject ENTYVIO SC if a healthcare professional determines it is appropriate. Patients and caregivers should be instructed to follow the directions for administration of ENTYVIO SC in the Instructions for Use section of the Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

- **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.

Reference: Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals.

*Only for patients with UC. Q2W=every 2 weeks; Q8W=every 8 weeks.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

ORDERING ENTYVIO IV

EntyvioCONNECT | Entyvio vedolizumab

After ENTYVIO has been approved for your patient, the way you'll order their IV prescription depends on whether you'll be administering the treatment in your office or sending your patient to an alternate site of care (ASOC) for treatment.

Buying, Bagging, and Billing

If you plan to administer your patient's ENTYVIO IV infusions in your office, there are 4 ways to get started.

Buy and Bill

Purchase the drug from a wholesaler and bill the health plan for the cost of the drug and any administration fee.

Brown Bagging

Send the prescription to an SP, which will ship the medication to the patient and bill the patient's health plan directly. In this scenario, it's up to the patient to bring the medication with them to your office for administration.

Medication sent directly to patient

White Bagging (ie, Drop-Ship Model)

Send the prescription to an SP, which will process the order and mail it to your office and bill the health plan directly.

Medication sent to your office

Clear Bagging

Have your SP fill and send the prescription to your office or ASOC.

Reference: Vizient. Buy, bill or bag? Considerations for specialty drug acquisition. https://newsroom.vizientinc.com/buy-bill-or-bag-considerations-for-specialty-drug-acquisition.htm. Accessed July 12, 2023.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

ORDERING ENTYVIO PEN FOR UC

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ENTYVIO Pen prescriptions are filled by SPs in our current distribution network. If you think a patient with UC would be a good candidate for SC injections for maintenance therapy, you can begin the process of transitioning them from IV infusions.

Before you send the prescription:

- Look at the list of participating SPs in the current distribution network. This list is always kept up to date on the **ENTYVIO Pen SP Information Sheet**, which you can use for guidance on choosing an SP
- Cross-check the SPs in the current distribution network against the ones in your patient's pharmacy network
- Conduct a BI (or see if the SP will do this for you) if necessary under the patient's pharmacy benefit. *EntyvioConnect* can also provide support to confirm coverage
- If SC coverage is already confirmed, file a PA 2-4 weeks before the patient's first scheduled SC dose

After completing the PA and confirming coverage or receiving confirmation from the SP, send the SP an electronic prescription for the single-dose prefilled pen.

After you send the prescription:

- Let patients know that someone from the SP will likely be contacting them to confirm details like shipping address and to discuss financial benefit requirements if applicable

For any questions about how to acquire the ENTYVIO Pen, reach out to your FRM. You can also connect with a Patient Support Manager at *EntyvioConnect* at **1-855-ENTYVIO (1-855-368-9846)**, Monday to Friday, from 8 AM to 8 PM ET (except holidays).

IMPORTANT SAFETY INFORMATION (cont'd)

- **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.

Please see additional Important Safety Information on pages 29-30.

ADMINISTERING ENTYVIO IV

EntyvioCONNECT | Entyvio vedolizumab

The process for verifying a patient's benefits and acquiring and billing for the prescription may differ depending on where ENTYVIO IV is administered.

If ENTYVIO is infused in a clinic different from your office, your office may be responsible for ensuring ENTYVIO is covered by the health plan. Once coverage is confirmed, the prescription and approved PA can be sent to the ASOC, which purchases ENTYVIO and submits the required reimbursement claims to the payer.

Prior to an infusion appointment, your office may perform the following:

- BI
- PA submission
- Appeals and denials
- Co-pay benefits

Office has on-site infusion capabilities

- Buy and bill or acquire through SP
- On-site infusion
- Schedule next IV therapy with patient

If buy and bill, submit claim for reimbursement

OR

HCP sends Rx to an ASOC

Drug administration	Post administration
ASOC: • Submits or reverifies PA, as needed • Buy and bill or acquire through SP • Administers product • Schedules next IV therapy with patient	If buy and bill, **ASOC** submits claim for reimbursement HCP stays in communication with ASOC to ensure patient is following prescribed treatment course

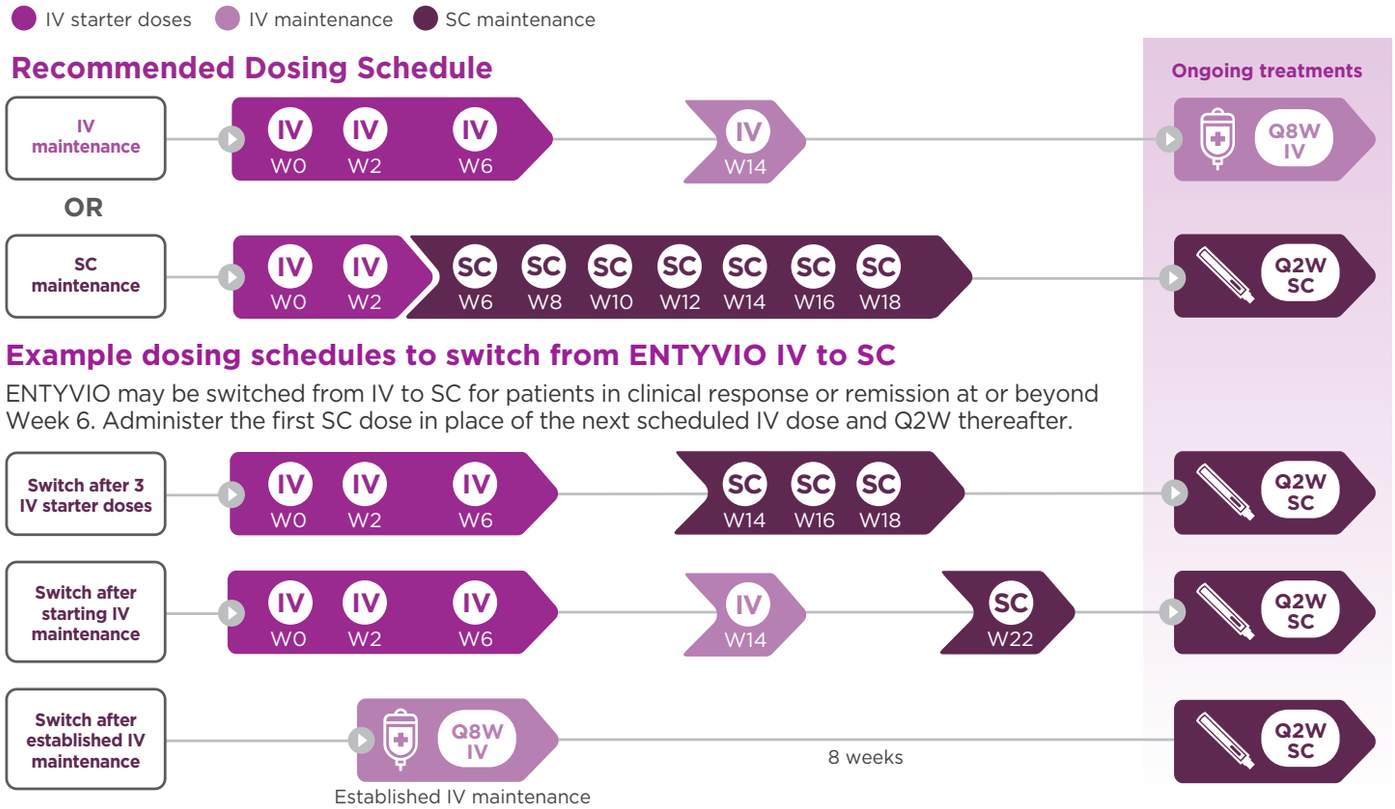
Use the **ENTYVIO Infusion Center Locator** to search criteria like proximity, operating hours, accepted insurance, and specific amenities.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

FLEXIBILITY IN UC ADMINISTRATION

EntyvioCONNECT | Entyvio vedolizumab



- Discontinue ENTYVIO in patients who do not show evidence of therapeutic benefit by Week 14

Prior to administration

Patients should be brought up-to-date with all immunizations prior to starting ENTYVIO IV or SC.

Concomitant therapies

ENTYVIO IV and SC can be administered concomitantly with aminosalicylates, steroids, and immunomodulators.

Administration

ENTYVIO is administered as a 300 mg flat dose over an approximately 30 minute IV infusion. Do not administer ENTYVIO as an IV push or bolus. ENTYVIO SC is administered as a 108 mg single-dose prefilled pen.

For complete Dosage and Administration information, please see Full Prescribing Information.

IMPORTANT SAFETY INFORMATION

- **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.

Reference: Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

EntyvioCONNECT | Entyvio vedolizumab

5 CLAIMS AND REIMBURSEMENT

Claims are a necessary part of enabling you to continue taking care of your patients.

> Completing a claims form
> Electronic filing and direct deposit for reimbursement

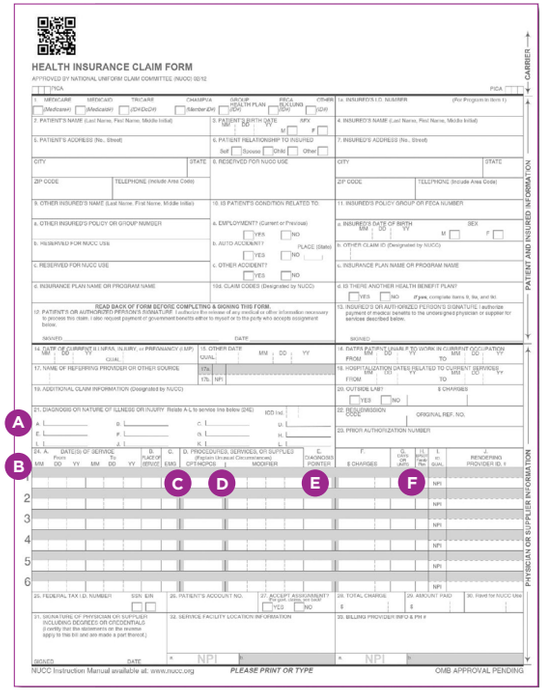
Please see additional Important Safety Information on pages 29-30.

COMPLETING A CLAIMS FORM

EntyvioCONNECT | Entyvio vedolizumab

The 2 claim forms shown here are the standard forms you'll use to **bill most government and private insurers and Medicare Fee-for Service** for services under a patient's medical benefit (ie, ENTYVIO IV treatment).

Completing a physician office CMS-1500 claim form



A Diagnosis Code | Box 21
Document appropriate ICD-10-CM diagnosis code(s) corresponding to the patient's diagnosis. Line A, primary diagnosis code

B Product Information | Box 24
Supplemental information may be entered in the shaded section. Providers must verify information requirements with the plan

C Product Code | Box 24D
Document use of product with appropriate code (eg, J code) depending on the plan

D Procedure Code | Box 24D
Use the CPT code representing the procedure performed, as required by the plan

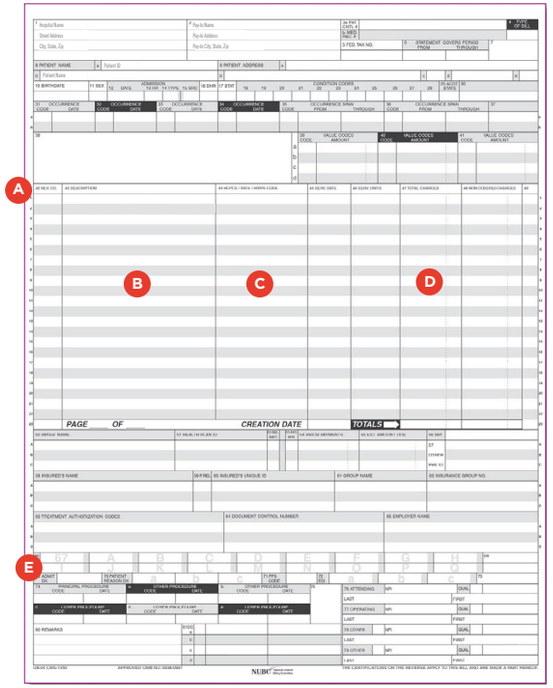
E Diagnosis Pointer | Box 24E
Specify diagnosis, from Box 21, related to each CPT/HCPCS code listed in Box 24D. This may be in a letter or number depending on the plan

F Service Units | Box 24G
Report number of units (300 units = one 300-mg vial)

SEE THE FULL CMS-1500 CLAIM FORM

INSTRUCTIONS ON HOW TO FILL OUT

Completing a hospital outpatient CMS-1450 (UB-04) claim form



A Revenue Codes | Box 42
List the 4-digit revenue code(s) in ascending order

B Description | Box 43
Enter a brief description that corresponds to the revenue code. List applicable NDC

C Product and Procedure Codes | Box 44
Appropriate HCPCS codes for Medicare or other plans. As it relates to administration procedure, use the CPT code representing the procedure performed

D Total Charges | Box 47
Enter the total amount charged for each line of service

E Diagnosis Code | Box 67
Enter the appropriate ICD-10-CM diagnosis code

SEE THE FULL UB-04 CLAIM FORM

INSTRUCTIONS ON HOW TO FILL OUT

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

ELECTRONIC DATA INTERCHANGE (EDI) AND ELECTRONIC FUNDS TRANSFER (EFT)

EntyvioCONNECT | Entyvio vedolizumab

Let *EntyvioConnect* help you **automate filing and getting reimbursed for your ENTYVIO commercial co-pay claims.**

USING EDI SIMPLIFIES THE CO-PAY SUBMISSION PROCESS AND ENSURES:

- EDI compliance
- An increase in accuracy of data and efficiency in information delivery
- A reduction in co-pay claim processing delays since errors can be corrected and resubmitted electronically
- Faster and direct receipt of claims outcomes
- Compatibility with your existing billing software

HAVE REIMBURSEMENTS DEPOSITED DIRECTLY INTO YOUR ACCOUNT THROUGH EFT AND:

- Automate claim payments from *EntyvioConnect*
- Reduce paperwork
- Reduce costs associated with manual processing time
- Get payments quickly and securely

EDI RESOURCE

The **EDI Guideline resource** outlines the features and steps of using an EDI to receive payment.

Ask your FRM about setting up EDI and EFT.

Please see additional Important Safety Information on pages 29-30.

Takeda Patient Support

EntyvioConnect Co-Pay Program Terms and Conditions

EntyvioCONNECT | Entyvio vedolizumab

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.

Please see additional Important Safety Information on pages 29-30.

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.

IMPORTANT SAFETY INFORMATION (cont'd)

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 (IV) Infusion: 300 mg vedolizumab
- ENTYVIO Subcutaneous (SC) Injection: 108 mg vedolizumab

Please click for Full Prescribing Information.

1 TREATMENT OPTIONS

2 *ENTYVIOCONNECT*

3 BENEFITS ROAD MAP

4 GETTING ENTYVIO TO YOUR PATIENTS

5 CLAIMS AND REIMBURSEMENT

6 IMPORTANT SAFETY INFORMATION

Takeda Patient Support