EntyvioCONNECT | Entyvio® vedolizumab

Connect with confidence

A how-to guide for enrolling your patients in *EntyvioConnect*

Please see Indications and Important Safety Information on page 9.

EntyvioConnect: Redefining the standard of caring when it comes to patient support

If your patients have been prescribed Entyvio, *EntyvioConnect* offers a range of available programs and services to support them throughout the entire treatment journey.

This *EntyvioConnect* Enrollment Guide provides an overview of the enrollment process and step-by-step instructions on how to complete the enrollment form. Refer to this resource if you have any questions regarding the information needed to complete the form.

***EntyvioConnect* partners with your patients throughout the entire insurance approval process.**

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**.

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

Please see Indications and Important Safety Information on page 9.

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Patients can enroll in *EntyvioConnect* online or in your office

ONE:
Enroll **online**

If your patient wants to enroll in *EntyvioConnect* on their own, direct them to **Entyvio.com/Register** to fill out the online form.

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

SECTION 1 — **CURRENT TREATMENT**

SECTION 2 — **SERVICE SELECTION**

- ❑ Co-Pay Program & Insurance Help
- ❑ Nurse Educator
- ❑ Text Message Treatment Reminders

Enrollment in EntyvioConnect gives your patients access to a range of other programs. *See **page 8** for details.*

SECTION 3 — **PATIENT CONTACT INFORMATION**

SECTION 4 — **PRESCRIBER INFORMATION**

SECTION 5 — **CONSENT AND HIPAA AUTHORIZATION**

Patient's digital signature is required.

Once all sections are filled out, your patients can sign up.

PRINT ON-DEMAND MEMBERSHIP ID CARD

If your patients are eligible for the Co-Pay Program, they will receive a confirmation page that includes a membership ID card that they will need to 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.

Please see Indications and Important Safety Information on page 9.

HIPAA=Health Insurance Portability and Accountability Act; ID=identification.

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Patients can enroll in *EntyvioConnect* online or in your office (cont'd)

TWO:
Enroll at **your office**

If your patient prefers to enroll at your office, you and your patient must complete the enrollment form and fax it to: **1-877-488-6814**.

SECTION 1

PATIENT INFORMATION

SECTION 2

PATIENT INSURANCE INFORMATION

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

SECTION 3

PRESCRIBER INFORMATION

- Include your tax ID # and NPI #

SECTION 4

INFUSION SITE INFORMATION

SECTION 5

PATIENT CLINICAL INFORMATION AND PRIOR THERAPIES

- Include previous therapies and the ICD-10-CM diagnosis codes. Please see **page 5** for relevant ICD-10-CM diagnosis codes

SECTION 6

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
- The prescriber signs on the line to confirm prescription decision:
  - Dispense as written
  - Substitution permitted

SECTION 7

PATIENT INFORMATION AND AUTHORIZATION

- Patient fills out personal information and contact details
- Patient can opt to receive an enrollment update from *EntyvioConnect*

SECTION 8

PATIENT HIPAA AUTHORIZATION

- Patient must sign both gray boxes to authorize compliance with HIPAA and to officially enroll in *EntyvioConnect*
- Patient can opt in for Nurse Support and/or to receive text message updates

Please see Indications and Important Safety Information on page 9.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NPI=National Provider Identifier.

Information on coding

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 payer's 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

Please see Indications and Important Safety Information on page 9.

Download an *EntyvioConnect* enrollment form.

FRONT

EntyvioConnect Enrollment and Prescription Form

FAX page 3 and page 4 to 1-877-488-6814
or call **1-855-ENTYVIO** (1-855-368-9846)
Monday through Friday, from 8 am to 8 pm ET (except holidays)

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1. PATIENT INFORMATION (COMPLETE AND SUBMIT PATIENT AUTHORIZATIONS ON PAGE 4)

Name (First, Middle Initial, Last) _____
Address _____
City/State/ZIP _____
Legal Representative Name (if applicable) _____

Birth Date (MM/DD/YYYY) _____ Gender ☐ Male ☐ Female
Email _____ Primary Phone _____
Legal Representative Primary Phone (if applicable) _____

2. PATIENT INSURANCE INFORMATION (FAX A COPY OF BOTH SIDES OF THE PRIMARY AND/OR SECONDARY INSURANCE CARD[S])

Primary Insurance Plan _____ Plan Phone _____
Subscriber Name _____
Birth Date _____ Relationship to Patient _____
Policy ID # _____ Group # _____
PA Reference # _____

Secondary or Prescription Plan _____ Plan Phone _____
Subscriber Name _____
Birth Date _____ Relationship to Patient _____
Policy ID # _____ Group # _____ **OR**
RxBIN _____ RxPCN _____ RxGroup _____

3. PRESCRIBER INFORMATION

Prescriber Name (First, Last) _____
Practice/Facility Name _____
Address _____
City/State/ZIP _____

Preferred Contact Name _____
Office Phone _____ Office Fax _____
Co-pay/Claims/AR Fax (if different from above) _____
Tax ID # _____ NPI # _____

4. INFUSION SITE INFORMATION (REQUIRED IF DIFFERENT FROM PRESCRIBER)

Treatment Provider Name (First, Last) _____
Practice/Facility Name _____
Address _____
City/State/ZIP _____

Description of site of care for infusion
☐ Hospital outpatient ☐ Infusion center ☐ Non-prescribing MD's office ☐ Patient home ☐ Other

Office Phone _____ Office Fax _____
Tax ID # _____ NPI # _____
Preferred Contact Name _____

5. PATIENT CLINICAL INFORMATION AND PRIOR THERAPIES

ICD-10-CM Diagnosis Code(s) _____
Current Medications _____

Prior therapies[2]: ☐ Humira® (adalimumab) ☐ 6-MP/azathioprine ☐ Cimzia® (certolizumab pegol) ☐ Remicade® (infliximab) ☐ Corticosteroids ☐ Stelara® (ustekinumab)
☐ Other _____

Medication Allergies, if any _____

6. DOSAGE AND DIRECTIONS FOR USE (REQUIRED FOR SPECIALTY PHARMACY TRIAGE)

Please complete Entyvio prescription information. Attach your prescription if this form does not comply with state laws (NY and NJ).

ENTYVIO IV PRESCRIPTION INFORMATION (COMPLETE THIS SECTION)

Dose	Dispense	Description
Initiation		
☐ Week 0: Infusion 300 mg IV	1 vial	14-day supply; 1 prescription, no refill
☐ Week 2: Infusion 300 mg IV	1 vial	30-day supply; 1 prescription, no refill
☐ Week 6: Infusion 300 mg IV	1 vial	30-day supply; 1 prescription, no refill
Maintenance		
☐ Infusion 300 mg IV	1 vial	60-day supply; 1 prescription, 6 refills

Please refer to the Entyvio Prescribing Information on how to reconstitute and dilute Entyvio for intravenous (IV) infusion.

Do you intend to buy and bill? ☐ Yes ☐ No

PRESCRIBER SIGNATURE

X _____ X _____

PRESCRIBER SIGNATURE (Dispense as written) **DATE** **PRESCRIBER SIGNATURE (Substitution permitted)** **DATE**

By signing this form, I certify that therapy with Entyvio is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current Entyvio Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to Entyvio therapy to Takeda Pharmaceuticals U.S.A., Inc., including its present and future affiliates, business partners, agents and contractors, for the purpose of seeking information related to coverage and/or assisting in initiating or continuing Entyvio therapy. I authorize EntyvioConnect *to transmit this prescription to the appropriate pharmacy designated by me, Patient (or his/her legal representative), or Patient's plan. I agree that product provided through the Program (if applicable) shall only be used for Patient, must not be resold, offered for sale or trade, or returned for credit, nor shall Patient nor any third-party payer, Medicare, or Medicaid be charged for this product. I have read, understand, and agree to the applicable Terms and Conditions. I understand that I am under no obligation to prescribe or purchase Entyvio or any other product manufactured by Takeda, and I certify I have received nothing of value from Takeda or its agents or representatives for prescribing a Takeda product.*

Please see Indications and Important Safety Information on page 9.

BACK

***EntyvioConnect* Enrollment and Prescription Form**
FAX page 3 and page 4 to 1-877-488-6814
or call **1-855-ENTYVIO** (1-855-368-9846)
Monday through Friday, from 8 am to 8 pm ET (except holidays)

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7. PATIENT INFORMATION AND AUTHORIZATION

Name (First, Middle Initial, Last) _____ Birth Date (MM/DD/YYYY) _____ Gender ☐ Male ☐ Female

Email _____ Okay to leave a message about the status of my enrollment or prescription? ☐ Yes ☐ No

Mobile Phone _____ Alternate Phone _____

8. PATIENT HIPAA AUTHORIZATION

By signing the Patient Authorization section on the second page of this *EntyvioConnect* Enrollment Form, I authorize my physician, health insurance, and pharmacy providers (including any specialty pharmacy that receives my prescription) to disclose my protected health information, including, but not limited to, information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form ("Protected Health Information"), to Takeda Pharmaceuticals U.S.A., Inc. and its present or future affiliates, including the affiliates and service providers that work on Takeda's behalf in connection with the *EntyvioConnect* Patient Support Program (the "Companies"). The Companies will use my Protected Health Information for the purpose of facilitating the provision of the *EntyvioConnect* Patient Support Program products, supplies, or services as selected by me or my physician and may include (but not be limited to) verification of insurance benefits and drug coverage, prior authorization education, financial assistance with co-pays, patient assistance programs, and other related programs. Specifically, I authorize the Companies to 1) receive, use, and disclose my Protected Health Information in order to enroll me in *EntyvioConnect* and contact me, and/or the person legally authorized to sign on my behalf, about *EntyvioConnect*; 2) provide me, and/or the person legally authorized to sign on my behalf, with educational materials, information, and services related to *EntyvioConnect*; 3) verify, investigate, and provide information about my coverage for Entyvio, including but not limited to communicating with my insurer, specialty pharmacies, and others involved in processing my pharmacy claims to verify my coverage; 4) coordinate prescription fulfillment; and 5) use my information to conduct internal analyses.

I understand that employees of the Companies only use my Protected Health Information for the purposes described herein, to administer the *EntyvioConnect* Patient Support Program or as otherwise required or allowed under the law, unless information that specifically identifies me is removed. Further, I understand that my healthcare provider may receive financial remuneration from Takeda Pharmaceuticals U.S.A. for marketing services. I understand that Protected Health Information disclosed under this Authorization may no longer be protected by federal privacy law. I understand that I am entitled to a copy of this Authorization. I understand that I may cancel this Authorization and that instructions for doing so are contained in Takeda's Website Privacy Notice available at www.takeda.com/privacy-notice/. I understand that such cancellation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from the date it is signed and provided on the first page of this enrollment form, unless a shorter period is provided for by state law. I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me. I also understand that if I do not sign this Authorization, I will not be able to receive *EntyvioConnect* Patient Support Program products, supplies, or services.

Patient Authorization I have read, understand, and agree to the release of my protected health information as described above.

x _____

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

Patient Support Program Enrollment

I have read, understand, and agree to the use of my personal information for the purposes described on page 5, section 9.

x _____

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

☐ Check this box if you wish to opt-in for *EntyvioConnect* Nurse Support

☐ Check this box if you wish to enroll in text message communication, as described on page 6, section 14

4

Please see Indications and Important Safety Information on page 9.

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Enrollment in *EntyvioConnect* gives your patients access to a range of programs throughout their treatment journey

Because each patient's circumstances vary, we offer a range of programs tailored to help patients in the way they need it most.

Insurance Support

- **Benefits investigation**
- **Prior authorization (PA) assistance**
- **Appeals and denials assistance**
- **Start Program*:** New-to-Entyvio patients who have received a denied PA from a commercial health plan are eligible
  - Entyvio 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
- **Bridge Program*:** Entyvio patients with a temporary loss or gap in commercial coverage or authorization are eligible
  - Provides Entyvio at no cost for up to 6 months
  - After 6 months, *EntyvioConnect* will look for available coverage assistance programs if needed

Affordability

- **Co-Pay Program:** Eligible patients may pay as little as **$5 per dose,**† up to a total benefit of $20,000 per year

Patient Education

- **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

*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.

Call **1-855-ENTYVIO** (1-855-368-9846) with any questions. *EntyvioConnect* Patient Support Managers are available Monday to Friday, from 8 am to 8 pm ET (except holidays).

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/mm^3 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 ≥3% and ≥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.

References: 1. Centers for Medicare & Medicaid Services. 2020 ICD-10-CM. Accessed March 23, 2020. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM. **2.** Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals.