EntyvioConnect Enrollment and Prescription Form

FAX page 1 and optional page 2 to 1-877-488-6814

or call 1-855-ENTYVIO (1-855-368-9846), Monday through Friday, 8 AM to 8 PM ET (except holidays)

EntyvioCONNECT | Entyvio® vedolizumab

For copay enrollment complete circled areas only*

Please select the patient and/or office support options you wish to receive from *EntyvioConnect*.

☐ Nurse Support Program ☐ Co-pay enrollment ☐ Patient Assistance Program ☐ Benefits investigation ☐ Prior authorization support ☐ Denial or appeal support

1. PATIENT INFORMATION AND AUTHORIZATION

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

Address _____ Email _____ Primary Phone _____

City/State/ZIP _____ Okay to leave a message about the status of my enrollment or prescription? ☐ Yes ☐ No

Legal Representative Name (if applicable) _____ Legal Representative Primary Phone (if applicable) _____

Patient Authorization

I have read, understand, and agree to the release of my protected health information, as described on page 3, section 9.

x _____

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

EntyvioConnect Patient Support Program and Communications Enrollment

I have read, understand, and agree to the use of my personal information for the purposes described on page 3, section 10.

x _____

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

2. PATIENT INSURANCE INFORMATION

Primary Insurance Plan _____ Plan Phone _____

Subscriber Name _____

Birth Date _____ Relationship to Patient _____

Policy ID # _____ Group # _____

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 CTGI

Address 30 Waterchase Dr

City/State/ZIP Rocky Hill, CT 06067

Preferred Contact Name Lisa Garand

Office Phone 860-257-4131 X2017 Office Fax 860-257-4159

Co-pay/Claims/AR Fax (if different from above) _____

PTAN # _____ Tax ID # 06-1411029 NPI # 1023124625

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

Treatment Provider Name (First, Last) _____

Practice/Facility Name _____

Address _____

City/State/ZIP _____

Preferred Contact Name _____

Office Phone _____ Office Fax _____

PTAN # _____ Tax ID # _____ NPI # _____

Description of site of care for infusion

☐ Hospital outpatient ☐ Infusion center ☐ Non-prescribing MD's office

☐ Patient home ☐ Other

5. PATIENT CLINICAL INFORMATION AND PRIOR THERAPIES

Prior therapies[1]: ☐ Humira ☐ 6-MP/azathioprine ☐ Cimzia ☐ Remicade ☐ Corticosteroids ☐ Stelara ☐ Other _____

ICD-10-CM Diagnosis Codes That May Be Appropriate to Describe Ulcerative Colitis[2]

☐ 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

Current Medications _____

ICD-10-CM Diagnosis Codes That May Be Appropriate to Describe Crohn's Disease[2]

☐ 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

☐ **Other ICD-10-CM Diagnosis Code** _____

6. DOSAGE AND DIRECTIONS FOR USE (REQUIRED FOR SPECIALTY PHARMACY BENEFIT OR THE PATIENT ASSISTANCE PROGRAM)

Please attach your prescription if this form does not comply with state laws (NY and NJ).

PRESCRIPTION INFORMATION FOR PATIENT (Check all 3 boxes for complete initiation schedule)		
Initiation	**Dispense**	**Description**
☐ 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	60-day supply; 1 prescription, no refill

PRESCRIPTION INFORMATION FOR PATIENT CURRENTLY BEING TREATED WITH ENTYVIO		
Maintenance	**Dispense**	**Description**
☐ Infusion 300 mg IV	1 vial	60-day supply; 1 prescription, up to 5 refills

ADDITIONAL INFORMATION

☐ Allergy _____

☐ Other _____

Do you intend to buy and bill? ☐ Yes ☐ No *If no, please provide:*

Preferred specialty pharmacy name not needed Phone _____

PRESCRIBER SIGNATURE – STAMPED SIGNATURE NOT ALLOWED

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 America, Inc., including its agents or 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 Patient's plan. Additionally, if Patient is eligible for the Patient Assistance Program ("PAP"), I understand that ENTYVIO® furnished through EntyvioConnect will be dispensed by the exclusive non-commercial pharmacy, must only be used for Patient, and must not be resold or offered for sale or trade, nor shall Patient nor any third-party payer, Medicare, or Medicaid be charged for this product.

x Not needed

PRESCRIBER SIGNATURE (Dispense as written. Substitution not allowed.) **DATE**

Please see Indications and Important Safety Information on page 4. For complete Dosage and Administration, please click here to see full Prescribing Information, including Medication Guide.

PATIENT ASSISTANCE PROGRAM FORM (OPTIONAL)

Patient lacks insurance coverage, is unemployed, or needs additional assistance; additional documentation may be required.

EntyvioCONNECT | Entyvio® vedolizumab

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(This page for govt insurances only and for use BEFORE infusion)

PATIENT NAME (First, Middle Initial, Last)

7. PATIENT INFORMATION

I am a US Resident ☐ Yes ☐ No

Number of people in household* _____

Total yearly household* income $ _____

*Household = you, spouse, and dependents.

Have you received Social Security Disability Income for at least 2 years?
☐ Yes ☐ No

Social Security Number† _____

†Required for electronic income verification.

☐ I do not wish to provide my Social Security Number. Please contact me to obtain alternate proof of income, which may include tax return, income statements, or other documents.

Do you have insurance from? (check all that apply)

☐ Employer ☐ State assistance ☐ Private drug coverage
☐ Medicaid ☐ Medicare ☐ None

8. PATIENT DECLARATIONS

PLEASE READ THE FOLLOWING CAREFULLY AND SIGN BELOW.
I declare and affirm that:

1. The information provided by me on this application form is true and accurate;
2. I give consent to the Program to disclose my enrollment in the Program as needed to comply with legal and regulatory obligations;
3. I agree to notify the Program immediately, in writing, if my prescription drug coverage changes in any way or if I discontinue use of Entyvio;
4. I will not seek or accept reimbursement from any health or prescription coverage plan, including a Medicare plan, for medication received from the Program;
5. I understand that if I am eligible or enrolled in a Medicare plan, I will
   a) receive the requested medication from the Program for the remainder of the enrollment calendar year for which my application was approved, and I will not seek the requested medication from my Medicare plan for the remainder of the enrollment calendar year;
   b) not seek true out-of-pocket (TrOOP) credit for any medication received from the Program because I understand that medication received from the Program will not count toward my TrOOP; and
   c) agree to notify my Medicare plan that I will receive my Takeda medication for free until the end of the year through the Program;
6. Unless I have checked the box asking for alternate means of income verification, I agree to allow Takeda and its Service Providers to use my demographic information, including but not limited to Social Security number, date of birth, name, and/or address as needed to access my credit information and information derived from public and other sources, including information from a consumer reporting agency (credit bureau), to estimate my income in conjunction with the eligibility determination process performed to determine my eligibility for the Program;
7. I understand the product will be shipped to the infusion site on my behalf.

X _____

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

9. PATIENT AUTHORIZATION

By signing the Patient Authorization section on the first 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 support, 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, assist with, and coordinate 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) assist with analysis related to Entyvio.

I understand that employees of the Companies only see my Protected Health Information to administer the *EntyvioConnect* Patient Support Program or as otherwise required or allowed under the law, unless information that specifically identifies me is removed. I understand that they will make every effort to keep my information private, but if it is accidentally shared with an associated party, my 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 Policy available at www.takeda.us/home/privacy_policy.aspx. 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 page one, 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.

10. *EntyvioConnect* PATIENT SUPPORT PROGRAM AND COMMUNICATIONS ENROLLMENT

1. I understand that the *EntyvioConnect* Patient Support Program is sponsored by Takeda Pharmaceuticals USA, Inc. and coordinated with affiliates and service providers that work on Takeda's behalf (the "Companies"). I understand that the Companies will need to use my personal information to enroll me in the program and provide the support I am asking for.
2. I authorize the Companies to use my personal information to provide me with information and offers related to Entyvio, the diseases and the conditions it treats, and related treatment options. In addition to information about Entyvio and related health conditions, I understand this may include information from Takeda, financial assistance programs, clinical trials and market research opportunities, and other support services or programs Takeda may in the future develop for patients.
3. I authorize Takeda to use my de-identified information to help Takeda improve and develop products, services, materials, and programs or for health economic outcomes and market research.
4. I understand that I can cancel my participation in the program at any time and can opt out of receiving future communications from Takeda by calling 1-855-ENTYVIO (1-855-368-9846). Once Takeda receives and processes my cancellation request, Takeda will not use my personal information going forward. I understand that canceling my participation will not affect any use of my information that occurred before my request was processed.
5. I am currently 18 years of age or older.

INDICATIONS: ENTYVIO (vedolizumab)

Adult Ulcerative Colitis (UC)

Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- inducing and maintaining clinical response
- inducing and maintaining clinical remission
- improving endoscopic appearance of the mucosa
- achieving corticosteroid-free remission

Adult Crohn's Disease (CD)

Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- achieving clinical response
- achieving clinical remission
- achieving corticosteroid-free remission

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 have occurred. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. If anaphylaxis or other serious allergic 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.
- Although no cases of PML have been observed in ENTYVIO clinical trials, JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. 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 click here for full Prescribing Information, including Medication Guide.

Reference: 1. Entyvio [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc. **2.** Centers for Medicare & Medicaid Services. ICD-10 Code Lookup. https://www.cms.gov/medicare-coverage-database/staticpages/icd-10-code-lookup.aspx. Accessed February 15, 2018.

April 2018 USD/VED/15/0201(1)e