Entyvio CONNECT vedolizumab

Enrollment and Prescription Form

FAX THIS FORM TO:
1-877-488-6814

All fields are required unless marked optional. If you have any questions, please reach out to your local Field Access Manager (FAM) or call **1-855-ENTYVIO (1-855-368-9846)**. *EntyvioConnect* Case Managers are available **Monday to Friday, from 8 AM to 8 PM ET** (except holidays).

1. PATIENT INFORMATION

First Name: _____ Last Name: _____

Legal Representative First Name and Last Name, if applicable: _____ Birth Date (MM/DD/YYYY): _____

_____ Email: _____

Home Address: _____ Phone: _____ Sex: ☐ Male ☐ Female

City: _____ State: _____ Zip Code: _____ ☐ Español es mi primer idioma

2. INSURANCE INFORMATION (PROVIDE A COPY OF THE FRONT AND BACK OF ALL INSURANCE CARDS AND SKIP TO SECTION 3)

Medical Insurance: _____ Policy #: _____ Group #: _____

Pharmacy Insurance: _____ PCN #: _____ GrpRX #: _____

Policy #: _____ Card/BIN #: _____

☐ **The patient has no insurance** and has checked eligibility requirements or applied to all available options for free or minimal cost insurance or other assistance. **NOTE:** For Patient Assistance Program (PAP) eligibility, please answer and return the Household Information on page 3.

3. CLINICAL INFORMATION

ENTYVIO®—DIAGNOSIS Select One: ☐ K51.90 Ulcerative Colitis, Unspecified ☐ K50.90 Crohn's Disease, Unspecified ☐ Other ICD-10 Code: _____

Treatment Start Date (MM/DD/YYYY): _____ ☐ Not yet started. Estimated start date (MM/DD/YYYY): _____

Current Medications, if any: _____

Medication Allergies, if any: _____

4. PRESCRIBER INFORMATION

Prescriber First Name: _____ **Prescriber Last Name:** _____

Prescriber NPI #: _____ **Office Phone:** _____ **Office Fax:** _____

Office Name: _____ **Office Contact Name (First, Last):** _____

Address: _____ **Office Tax ID #** (optional): _____

City: _____ **State:** _____ **Zip Code:** _____ **Office Contact Email:** _____

5. PRESCRIPTION INFORMATION

STEP 1: INTRAVENOUS INITIATION: ENTYVIO (VEDOLIZUMAB)

INTRAVENOUS INITIATION: Check: ☐ 300 mg IV at weeks 0 and 2 Vials # (for 1 infusion): 1 Refills: 1

Infusion Site: (ONLY REQUIRED IF DIFFERENT FROM PRESCRIBER'S OFFICE. Shipments cannot be sent to PO boxes.)

☐ Nonprescriber's Office ☐ Hospital Outpatient ☐ Infusion Center ☐ Other ☐ Site is same as prescriber (If checked, no further information needed)

Physician or Infusion Provider Name: _____ **Site Contact Name:** _____

Site Name: _____ **Site NPI #:** _____ **Site Tax ID #:** _____

Address: _____ **City:** _____ **State:** _____ **Zip Code:** _____

Phone: _____ **Site Fax:** _____

STEP 2: MAINTENANCE THERAPY OPTIONS (CHOOSE ONE): ENTYVIO (VEDOLIZUMAB)

SUBCUTANEOUS MAINTENANCE: Check: ☐ 108 mg SC at week 6, then every 2 weeks thereafter: 2 **pens per dispense** Refills: 13

OR INTRAVENOUS MAINTENANCE: Check: ☐ 300 mg IV at week 6, then every 8 weeks thereafter: 1 **vial per infusion** Refills: 7

☐ **COMMERCIAL SPECIALTY PHARMACY (SP) OPT-OUT:** By checking this box, the prescriber requests benefits investigation only and does NOT want *EntyvioConnect* to triage the ENTYVIO Pen prescription to a Specialty Pharmacy.

If a specific SP is NOT mandated by the patient's payer, please enter the name of a preferred SP: _____

If an SP is not indicated above, an EntyvioConnect *preferred SP will be selected for the patient.*

PRESCRIBER SIGN HERE X _____ _____

PRESCRIBER SIGNATURE (Dispense as written) **DATE (MM/DD/YYYY)**

- *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 agents or contractors (the "Company"), 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 representative), or Patient's plan. I agree that product provided through the Program shall only be used for Patient, and 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 understand that I am under no obligation to prescribe ENTYVIO or any other product manufactured by the Company, and I certify I have received nothing of value from the Company or its agents or representatives for prescribing a Company product.*
- *I authorize* EntyvioConnect, *as my designated agent and on behalf of my patients to forward a prescription for ENTYVIO, by fax or other mode of delivery, to Sonexus Health Pharmacy Services.*

Authorization for Takeda Patient Support

6. PATIENT HIPAA AUTHORIZATION

By signing the Patient Authorization section of this *EntyvioConnect* 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 physician, health insurance, and pharmacy providers may receive financial remuneration from the Companies for providing Protected Health Information, which may be used for marketing purposes. 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 can also revoke my Authorization by emailing PrivacyOffice@takeda.com, by calling 1-855-268-1825, or by sending written notice of revocation to *EntyvioConnect*, PO Box 2355, Morristown, NJ 07962. I may revoke this Authorization at any time by sending written notice of revocation to *EntyvioConnect*, PO Box 2355, Morristown, NJ 07962. 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 below, 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 HIPAA Authorization I have read, understand, and agree to the release of my Protected Health Information as described above.

PATIENT SIGN HERE X _____

PATIENT SIGNATURE/LEGAL REPRESENTATIVE SIGNATURE (indicate relationship) **DATE** (MM/DD/YYYY)

7. PATIENT SUPPORT PROGRAM ENROLLMENT

By signing below, I acknowledge I have read the *EntyvioConnect* Patient Support Services Terms & Conditions (www.entyvio.com/enrollment-terms) and choose to enroll. I authorize the use and disclosure of my personal and health information to provide services that may include insurance benefit and drug coverage verification, prior authorization support, financial assistance programs, disease state or product education, and communications with me or my prescribing physician by mail, email, or phone about my care, treatment, product information, or health insurance. I understand Takeda and its business partners may use and share my personal and health information with my healthcare providers, pharmacies, and health insurance plans to support my care, to meet its legal obligations, and de-identified data for internal use.

PATIENT SIGN HERE X _____

PATIENT SIGNATURE/LEGAL REPRESENTATIVE SIGNATURE (indicate relationship) **DATE** (MM/DD/YYYY)

8. NURSE SUPPORT ENROLLMENT (OPTIONAL)

☐ By checking this box, I would like to enroll in Nurse Support. I understand that if I elect to receive Injection Training, I agree to attend in person with an *EntyvioConnect* nurse or via online, on a secure platform provided by *EntyvioConnect*.

9. TEXT MESSAGING AGREEMENT TERMS & CONDITIONS (OPTIONAL)

☐ By checking this box, you agree to these Takeda Patient Support (the "Program") text message terms and conditions, you agree to receive text messages on your mobile device subject to the Terms & Conditions described below. You also consent to receive autodialed and/or pre-recorded calls and/or text messages from or on behalf of the Program at the telephone number provided above. You understand that this consent is not a condition of purchase or use of the Program or of any Takeda product or service. Participants will receive an average of 5 text messages each month while enrolled in the Program. Such messages may be nonmarketing messages related to the Patient Support Program. There is no fee payable to Takeda to receive text messages; however, your carrier's message and data rates may apply. You represent that you are the account holder for the mobile telephone number(s) that you provide to opt-in to the Program. You are responsible for notifying Takeda immediately if you change your mobile telephone number. You may notify Takeda of a number change by calling 1-855-ENTYVIO. Data obtained from you in connection with your registration for, and use of, this SMS service may include your phone number and/or email address, related carrier information, and elements of pharmacy claim information and will be used to administer this Program and to provide Program benefits such as information about your prescription, refill reminders, and Program updates and alerts. Takeda will not be liable for any delays in the receipt of any SMS messages, as delivery is subject to effective transmission from your network operator. This Program is valid with most major US cellular providers. Takeda may be required to contact the user if an adverse event is reported. You agree to indemnify Takeda and any third parties texting on its behalf in full for all claims, expenses, and damages related to or caused, in whole or in part, by your failure to immediately notify us if you change your telephone number, including but not limited to all claims, expenses, and damages related to or arising under the Telephone Consumer Protection Act. Takeda reserves the right to rescind, revoke, or amend the Program without notice at any time. You can unsubscribe from receiving text messages by texting STOP. For questions about this Program, text HELP or contact the customer support center at 1-855-ENTYVIO.

ENTYVIO Patient Assistance Program

Provide the # of people in household (patient, spouse, and dependents): _____

SIGNATURE BELOW REQUIRED FOR PATIENTS APPLYING FOR PAP

At Takeda, we believe all patients should have access to the medications prescribed by their healthcare providers. We also understand that some patients may have financial situations that make it difficult to pay for their prescriptions. The ENTYVIO Patient Assistance Program ("ENTYVIO PAP") provides assistance for people who have no insurance or who do not have enough insurance and need help getting their Takeda medications. All applications are reviewed on a case-by-case basis in accordance with program criteria. If you are currently covered for an ENTYVIO formulation, you may not be eligible for the Patient Assistance Program.

TO BE ELIGIBLE, ENTYVIO IV AND/OR PEN PATIENTS MUST MEET ALL OF THESE CONDITIONS:

- Be a resident of the United States
- Meet income criteria
- Not have access to alternative sources of coverage or funding
- Not be enrolled in an alternate funding or similar program. If you 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 general, not have health coverage through private or government programs
- Other terms and conditions apply

Applicants who are not approved for enrollment in the program may have the opportunity to seek an exception to the general program criteria. This program can be discontinued or changed at any time without notice at the discretion of Takeda Pharmaceuticals U.S.A., Inc.

10. PATIENT DECLARATIONS (IF ELIGIBLE, PLEASE READ THE FOLLOWING STATEMENTS 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 application 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;
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 application 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 application 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. I understand the IV product will be shipped to the infusion site on my behalf;
7. I understand that Takeda and its business partners will use my personal information to enroll me in the Patient Support Program, provide the support I am asking for, and offer related services to me;
8. Patients can opt-in (on page 2) to be paired with a Nurse Educator and receive guidance throughout their treatment on ENTYVIO. SC injection education for the ENTYVIO Pen can also be provided either virtually or in-home when applicable. Our nurses do not provide medical advice;
9. I want Takeda Entyvio Patient Assistance Program ("PAP") to conduct e-income verification, which will include a soft credit check to determine household income. I understand that I am hereby providing "written instructions," under the Fair Credit Reporting Act (FCRA), authorizing the PAP and its vendors to run a soft credit check or other information about me from (third-party service providers) for the purpose of determining my financial eligibility for the PAP. I understand that I must affirmatively agree to these terms in order to proceed in this financial screening process for the PAP. I also understand that I may need to provide additional documentation and that additional eligibility requirements apply for the PAP;
10. All information provided is accurate, I agree to comply with the Terms and Conditions (found at www.entyvio.com/enrollment-terms) of the ENTYVIO PAP, and all information provided in connection with the patient's application to the ENTYVIO PAP is accurate.

PATIENT SIGN HERE X _____

PATIENT SIGNATURE/LEGAL REPRESENTATIVE SIGNATURE (indicate relationship) **DATE** (MM/DD/YYYY)

Takeda does not charge patients a fee for its assistance. Takeda is not affiliated with third parties who charge a fee for assistance with enrollment or medication refills. If you are being charged a monthly fee for support from Takeda, the organization billing you is not Takeda and you are being charged for support that Takeda can provide to you directly at no cost.

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