Patient Assistance Program Application Form

CAN I APPLY?

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, you 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
- In general, not have health coverage through private or government programs
- Other terms and conditions apply (see section 10)

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.

For Indications and Important Safety Information, please see page 7; for complete dosage and administration, please click to read the full Prescribing Information, including Medication Guide.

Entyvio® vedolizumab

ENTYVIO Patient Assistance Program

PO Box 501847, San Diego, CA 92150 | **Phone:** 1-855 ENTYVIO (855-368-9846) | **Fax:** 1-877-488-6814

Patient Assistance Program representatives are available: Monday to Friday, from 8 AM to 8 PM ET (except holidays)

1. PATIENT INFORMATION (COMPLETE PATIENT INFORMATION, SIGNATURES, AND AUTHORIZATIONS IN SECTIONS 6, 7, 8, AND 9)

First Name: _____ **Middle Initial:** _____

Last Name: _____

Home Address: _____

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

PLEASE NOTE: For patients receiving the ENTYVIO Pen for subcutaneous (SC) injections, shipping information will be confirmed with the patient by the specialty pharmacy.

Legal Representative Name (if applicable): _____

Legal Representative Primary Phone: _____

Birth Date (MM/DD/YYYY): _____

Sex*: ○ Male ○ Female **U.S. Resident:** ○ Yes ○ No

Primary Phone: _____ ○ Mobile ○ Home ○ Office

Other Phone: _____ ○ Mobile ○ Home ○ Office

Email: _____

Preferred Form of Contact: ○ Phone ○ Text ○ Email

Is it OK to leave a detailed voice message about the status of your application, prescription, or shipments on your phone? **Check all that apply:**

☐ Yes, Primary Phone ☐ Yes, Other Phone ☐ No

Preferred time (select one): ○ Morning ○ Day ○ Evening

*Takeda and its partners recognize that patients may not identify as male or female. However, many insurance companies still require that one of these 2 fields be used for each of their members. Please indicate the sex on file with the patient's insurance company.

2. PRESCRIBER INFORMATION (COMPLETE PRESCRIBER INFORMATION AND SIGNATURES IN SECTIONS 2, 3, 4, AND 5)

Prescriber First Name: _____

Prescriber Last Name: _____

Practice/Facility Name: _____

Address: _____

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

Preferred Contact Name: _____

Office Phone: _____ **Office Fax:** _____

Tax ID #: _____

NPI #: _____

State License #: _____ **Exp Date:** _____

Prescriber OR Preferred Email: _____

PLEASE NOTE: The ENTYVIO Pen will be shipped directly to patients.

ENTYVIO intravenous (IV) ship to location (select one): ○ Prescriber office above ○ Infusion site below

3. ENTYVIO IV INFUSION SITE INFORMATION (MUST COMPLETE IF DIFFERENT FROM PRESCRIBER INFORMATION)

Description of infusion site of care (select one):

○ Hospital outpatient ○ Infusion center ○ Nonprescribing MD's office ○ Patient home ○ Other

Treatment Provider First Name: _____

Treatment Provider Last Name: _____

Practice/Facility Name: _____

Address: _____

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

Preferred Contact Name: _____

Office Phone: _____ **Office Fax:** _____

Tax ID #: _____

NPI #: _____

Facility DEA: _____

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PATIENT

Name: _____ DOB: _____ ZIP: _____

4. PATIENT CLINICAL INFORMATION (REQUIRED)

Medication Allergies, If Any: _____

Current Medications: _____

5. DOSAGE AND DIRECTIONS FOR USE (REQUIRED)

Please review options below and only fill out one of the tables (either IV or the ENTYVIO Pen prescription information). Attach your prescription if this form does not comply with state laws (NY and NJ). NOTE: In certain circumstances this prescription may need to be validated and/or verified.

ENTYVIO INTRAVENOUS (IV) INFUSION

Dose	Directions	Dispense
Initiation		
☐ Week 0 and 2: Infusion 300-mg IV	Infuse 1 vial IV at Week 0 and Week 2	2 vials, 0 refills
☐ Week 6: Infusion 300-mg IV	Infuse 1 vial IV at Week 6	1 vial, 0 refills
Maintenance		
☐ Infusion 300-mg IV	Infuse 1 vial IV every 8 weeks	1 vial, 6 refills
Date of last IV infusion (if applicable): _____ and date of next IV infusion: _____		
☐ Other: _____ mg for every _____ weeks		Qty:___ vial(s), refills:___

Please refer to the ENTYVIO Prescribing Information on how to reconstitute and dilute ENTYVIO for Infusion.

ENTYVIO PEN FOR SUBCUTANEOUS (SC) INJECTION

Dose	Directions	Dispense
If the patient has received at least 2 doses of ENTYVIO IV, please provide the following:		
Dates of last 2 IV infusions: _____ and _____ ; next IV infusion date (if applicable): _____		
Initiation		
☐ Week 0 and 2: Infusion 300-mg IV	Infuse 1 vial IV at Week 0 and Week 2	2 vials, 0 refills
☐ Week 6: Infusion 300-mg IV	Infuse 1 vial IV at Week 6	1 vial, 0 refills
Maintenance		
☐ Prefilled Pen 108 mg	Inject 1 pen SC every 2 weeks	2 pens, 13 refills
Date of last SC injection (if applicable): _____ and date of next SC injection: _____		
☐ Other: _____ mg for every _____ weeks		Qty:_____, refills:____

Please refer to the ENTYVIO Prescribing Information for the recommended Dosage and Administration of ENTYVIO.

PLEASE NOTE: If you are currently covered for an ENTYVIO formulation, you may not be eligible for the Patient Assistance Program.

ENTYVIO SC formulation is intended to treat adults with moderate to severe ulcerative colitis. Injections are self-administered or given by a caregiver. The patient or caregiver should be trained by a healthcare professional. *EntyvioConnect* provides free injection education either virtually or in-home to all **eligible ENTYVIO patients when they opt in for Nurse Support**. Patients can opt in by checking the box on page 6 underneath the signature line.

X _____

Prescriber Name (Print): **NPI #:**

X _____

PRESCRIBER SIGNATURE (Dispense as written) **Date**

By signing this form, I certify that therapy with ENTYVIO is medically necessary for the subject patient. I have reviewed the current ENTYVIO Prescribing Information and will be supervising the patient's treatment. I understand that ENTYVIO furnished through the ENTYVIO Patient Assistance Program will be dispensed by the exclusive noncommercial pharmacy. Additionally, I certify that if the product is sent to my office on behalf of the patient, I understand that it must be used for the patient listed on this application, and not to be resold or offered for sale or trade, nor shall the patient nor any third-party payer, Medicare, or Medicaid be charged for this product.

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PATIENT

Name: _____ DOB: _____ ZIP: _____

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

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

☐ Employer supplied ☐ Medicare ☐ State assistance ☐ Military benefits ☐ Other

☐ Private insurance ☐ Medicaid ☐ Health exchange plan ☐ VA benefits ☐ None

Primary Insurance Plan: _____

Plan Phone: _____

Subscriber Name: _____

Birth Date (MM/DD/YYYY): _____ **Relationship to Patient:** _____

Policy ID #: _____ **Group #:** _____

PA Reference #: _____

Secondary or Prescription Plan: _____

Plan Phone: _____

Subscriber Name: _____

Birth Date (MM/DD/YYYY): _____ **Relationship to Patient:** _____

Policy ID #: _____ **Group #:** _____ **OR**

RxBIN: _____ **RxPCN:** _____ **RxGroup:** _____

7. PATIENT INCOME INFORMATION

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

IMPORTANT: Do you have a copy of last year's federal income tax return? ○ Yes ○ No

☐ If you marked **YES**, you must include a copy of either:

- Last year's federal income tax return(s) for yourself, your spouse, and your dependents, **OR**
- If your income has changed significantly, or if you are no longer employed, send a new income statement or proof of unemployment

☐ If you do **NOT** receive federal income tax returns, you must include a copy of:

○ IRS Form 4506T **OR** ○ Social Security Benefit Statement (SSA-1099) **OR** ○ Four consecutive weeks of recent pay stubs

8. PATIENT DECLARATIONS (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. All information provided is accurate, I agree to comply with the terms of the ENTYVIO PAP, and all information provided in connection with the patient's application to the ENTYVIO PAP is accurate.

X _____

Patient Signature (or Legal Representative Signature [indicate relationship]) **Date**

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PATIENT
Name: _____ DOB: _____ ZIP: _____

9. PATIENT HIPAA AUTHORIZATION AND CERTIFICATION (PLEASE READ THE FOLLOWING STATEMENT CAREFULLY AND SIGN BELOW)

By signing the Patient Authorization section of this *EntyvioConnect* Form on page 6, 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 revoke this Authorization and that instructions for doing so are contained in Takeda's Website Privacy Notice available at www.takeda.com/privacy-notice/ or I may revoke this Authorization at any time by sending written notice of revocation to *EntyvioConnect*, PO Box 13185, La Jolla, CA 92039-3185. I understand that such revocation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire at the earliest of what is required by state law, and never in any case longer than 5 years. 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. TERMS OF PARTICIPATION

The ENTYVIO Patient Assistance Program ("ENTYVIO PAP") provides free medicine to qualifying patients based on financial need. Participation in the ENTYVIO PAP is free; we do not collect any fees from people seeking our assistance. In applying for the ENTYVIO PAP, you agree that the program is intended solely for the benefit of you—not health plans and/or their partners. Other than the patient, only the patient's legal guardians, authorized caregivers, prescribing physician or the prescribing physician's staff, or the patient's power of attorney can complete the ENTYVIO PAP application and apply for free medicine. If you have enrolled in an alternate funding program or similar program that purports to help manage costs, or requires you to apply to a manufacturers' patient assistance program, or otherwise pursue specialty drug prescription coverage through an alternate funding vendor as a condition of, requirement for, or prerequisite to coverage of ENTYVIO, then you are not eligible for the ENTYVIO Patient Assistance 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. It may be possible that you are unaware whether you are subject to these programs. Takeda will monitor program utilization data and reserves the right to discontinue assistance at any time. If Takeda determines that you are subject to an alternate funding program or similar program, or the information provided to ENTYVIO PAP is inaccurate, Takeda may discontinue assistance at any time. The program may be changed or discontinued without notice. Takeda reserves the right to change or end the ENTYVIO PAP Program at any time without notice, and other terms and conditions may apply.

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11. TEXT MESSAGE COMMUNICATIONS

By agreeing to these *EntyvioConnect* (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. You can unsubscribe from receiving text messages by texting STOP. You will remain enrolled in the *EntyvioConnect* Patient Support Program. For questions about this Program, text HELP or contact the customer support center at 1-855-ENTYVIO.

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 into 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, as well as 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 U.S. carriers, including Verizon Wireless, Sprint, Nextel, Boost Mobile, T-Mobile®, AT&T, Alltel, ACS Wireless, Bluegrass Cellular, Carolina West Wireless, CellCom, Cellular One of East Central Illinois (ECIT), Cincinnati Bell, Cricket, C-Spire Wireless, Duet IP (aka Max/Benton/Albany), Element Mobile, Epic Touch, GCI Communications, Golden State, Hawkeye (Chat Mobility), Hawkeye (NW Missouri Cellular), Illinois Valley Cellular (IVC), Inland Cellular, iWireless, Keystone Wireless (Immis/PC Management), MetroPCS, MobiPCS, Mosaic, MTPCS/Cellular One (Cellone Nation), Nex-Tech Wireless, nTelos, Panhandle Telecommunications, Pioneer, Plateau, Revol Wireless, Rina-Custer, Rina-All West, Rina-Cambridge Telecom Coop, Rina-Eagle Valley Comm, Rina-Farmers Mutual Telephone Co, Rina-Nucla Nutria Telephone Co, Rina-Silver Star, Rina-South Central Comm, Rina-Syringa, Rina-UBET, Rina-Manti, Simmetry, South Canaan/CellularOne of NEPA, Thumb Cellular, Union Wireless, United Wireless, U.S. Cellular, Viaero Wireless, Virgin Mobile, and West Central Wireless (includes Five Start Wireless).

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 cause, 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 this Program by texting STOP. For questions about this Program, text HELP or contact the customer support center at 1-855-ENTYVIO.

12. VIDEO EDUCATION

Patients participating in virtual injection education agree to attend via an online, secure platform provided by *EntyvioConnect*.

Patient HIPAA Authorization
I have read, understand, and agree to the release of my protected health information as described on page 5, section 9.

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

Text Communication Enrollment
I have read, understand, and agree to opt in for text communications as described on page 6, section 11.

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

☐ **Check this box if you wish to opt in to enroll in ENTYVIO Nurse Support. Patients participating in virtual injection education agree to attend via an online, secure platform provided by *EntyvioConnect*.**

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- **Infections:** Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.
- **Progressive Multifocal Leukoencephalopathy (PML):** PML, a rare and often fatal opportunistic infection of the central nervous system (CNS), has been reported with systemic immunosuppressants, including another integrin receptor antagonist. PML typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported. Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms that may include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- **Liver Injury:** There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.
- **Live and Oral Vaccines:** Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥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.