



**ENTYVIO Patient Assistance Program**  
 P.O. Box 13185, La Jolla, CA 92039-3185  
 Phone: 1-855-ENTYVIO (855-368-9846)  
 Fax: 1-877-488-6814

Patient Assistance Program  
 representatives are available  
 Monday – Friday  
 8:00 a.m. – 8:00 p.m. EST



**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 ("Program") provides assistance for people who have no insurance or who do not have enough insurance and need help getting their Takeda medicines. All applications are reviewed on a case-by-case basis in accordance with program criteria.

To be eligible, you must:

- Be a resident in the United States
- Not have access to alternate sources of coverage or funding
- Meet income criteria (Household income of 500% Federal Poverty Level)
- In general, not have health coverage through private or government programs

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 America, Inc.

**SECTION 1: PRESCRIBER INFORMATION**

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_ Clinic Name (if applicable): \_\_\_\_\_  
 Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_  
 Phone: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_ Fax: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_ NPI #: \_\_\_\_\_  
 Tax ID #: \_\_\_\_\_ State License #: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

**SHIP TO INFORMATION (where patient will be infused):**

Ship To:  Physician Office Above  Facility indicated below Facility DEA: \_\_\_\_\_  
 Facility Name: \_\_\_\_\_ Facility Contact Name: \_\_\_\_\_  
 Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_  
 Phone: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_ Fax: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_ NPI #: \_\_\_\_\_

**SECTION 2: PRESCRIPTION INFORMATION (NJ and NY Physicians please attach appropriate prescription)**

Patient Name: _____ Birth Date: _____ / _____ / _____ <small style="margin-left: 100px;">MM DD YEAR</small>	<b>Induction Phase: ENTYVIO 300 mg IV (300 mg single-use vial)</b> <b>Maintenance Phase: ENTYVIO 300 mg IV (300 mg single-use vial)</b>
<b>Dispense:</b> <input type="checkbox"/> Prescription #1 and Prescription #2 Prescription #1: PAP Specialty Pharmacy will dispense 2 vials in the first prescription for Infusion Week 0 and Week 2 Prescription #2: PAP Specialty Pharmacy will dispense 1 vial for Infusion Week 6 <b>Dosage and Directions for Use:</b> <input type="checkbox"/> Infusion 300 mg IV on Week 0, Week 2, Week 6 <input type="checkbox"/> Other _____	<b>Dispense:</b> <input type="checkbox"/> Qty: 1 vial Refill _____ times <b>Dosage and Directions for Use:</b> <input type="checkbox"/> Maintenance Infusion 300 mg IV every 8 weeks <input type="checkbox"/> Other _____ Has patient completed Induction phase <input type="checkbox"/> Yes / <input type="checkbox"/> No

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 non-commercial 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 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.



Healthcare Provider Signature (Stamped Signatures NOT ACCEPTED)

Date

For full Indications and Important Safety Information, please see page 4; for complete dosage and administration, please click here to read the full [Prescribing Information](#), including [Medication Guide](#).



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**SECTION 3: PATIENT INFORMATION**

Patient Name: \_\_\_\_\_  
 Home Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_  
 Daytime Phone: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_ Birth Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Gender: M  F  U.S. Resident: Yes  No   
MM DD YEAR

**SECTION 4: INSURANCE AND INCOME**

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

- Employer supplied       Medicare       Medicaid       Military benefits       VA benefits       Other  
 Private drug coverage/employer supplied       State assistance       None       Health exchange plan

Number of people in household\*: \_\_\_\_\_ Total yearly household\* income: \$ \_\_\_\_\_ \*Household = you, spouse and dependents

Have you received Social Security Disability Income for at least two 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 last year’s federal income tax return(s) for yourself, your spouse and your dependents. If your income has changed significantly, or if you are no longer employed, send a new income statement or proof of unemployment.

If you marked NO, you must include a copy of:

- IRS Form 4506T or  Social Security Yearly Benefits Statement (SSA-1099) or  All income statements from jobs held last year

**SECTION 5: 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 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;
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. I understand the product will be shipped to the infusion site on my behalf.



\_\_\_\_\_  
 Patient Signature (or Legal Representative Signature (indicate relationship))

\_\_\_\_\_  
 Date

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**SECTION 6: PATIENT HIPAA AUTHORIZATION AND CERTIFICATION**

PLEASE READ THE FOLLOWING STATEMENT CAREFULLY AND SIGN BELOW

Permission for Sharing Personal Health Information: 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 Assistance Program (the "Companies"). The Companies will use my Protected Health Information for the purpose of facilitating the provision of the EntyvioConnect Patient Assistance Program (the "Program") products, supplies, or services as selected by me or my physician. Specifically, I authorize the Companies to 1) receive, use, and disclose my Protected Health Information in order to enroll me in the Program and contact me, and/or the person legally authorized to sign on my behalf, about the Program; 2) provide me, and/or the person legally authorized to sign on my behalf, with educational materials, information, and services related to the Program; 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 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](http://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 the Program products, supplies, or services.



\_\_\_\_\_  
 Patient Signature (or Legal Representative Signature (indicate relationship))

\_\_\_\_\_  
 Date

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## ENTYVIO (vedolizumab)

### INDICATIONS

#### Adult Ulcerative Colitis (UC)

ENTYVIO (vedolizumab) is indicated in 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 for inducing and maintaining clinical response, inducing and maintaining clinical remission, improving endoscopic appearance of the mucosa, and achieving corticosteroid-free remission.

#### Adult Crohn's Disease (CD)

ENTYVIO (vedolizumab) is indicated in 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 for achieving clinical response, achieving clinical remission, and 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  $\geq 3\%$  and  $\geq 1\%$  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.

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