Entyvio® vedolizumab

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 am to 8 pm ET

Takeda

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
- ☐ Meet income criteria (Household income of 500% Federal Poverty Level)
- ☐ Not have access to alternate sources of coverage or funding
- ☐ 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 U.S.A., 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: _____ (MM) / _____ (DD) / _____ (YEAR)

Induction Phase: ENTYVIO 300 mg IV (300 mg single-use vial)

Dispense:

☐ 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

Dosage and Directions for Use:

☐ Infusion 300 mg IV on Week 0, Week 2, Week 6
☐ Other _____

Maintenance Phase: ENTYVIO 300 mg IV (300 mg single-use vial)

Dispense:

☐ Qty: 1 vial Refill _____ times

Dosage and Directions for Use:

☐ Maintenance Infusion 300 mg IV every 8 weeks
☐ Other _____
Has patient completed Induction phase ☐ Yes / ☐ 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 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.

SECTION 3: PATIENT INFORMATION

Patient Name: _____

Home Address: _____ City: _____ State: _____ ZIP: _____

Daytime Phone: (_____) _____ - _____ Birth Date: ____/____/_____ (MM/DD/YEAR) Gender: M ☐ F ☐ U.S. Resident Yes ☐ No ☐

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

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.

SECTION 6: PATIENT HIPAA AUTHORIZATION AND CERTIFICATION

PLEASE READ THE FOLLOWING STATEMENT CAREFULLY AND SIGN BELOW

Permission for Sharing Personal Health Information: By signing this Patient Authorization section, 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, 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 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 https://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, 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

For appropriate adult patients with moderate to severe ulcerative colitis or Crohn's disease when other therapies 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 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 click here to read the 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.