1 BENEFIT INVESTIGATION ENROLLMENT FORM

Entyvio CONNECT | Entyvio® vedolizumab

PATIENT INFORMATION (PLEASE ATTACH AN ENLARGED COPY OF THE FRONT AND BACK OF THE PATIENT'S INSURANCE CARD AND/OR OTHER INSURANCE INFORMATION ALONG WITH THIS FORM)			☐ **Coverage Inquiry Only**
Patient Name (First, Middle Initial, Last):			
Home Address:	City:	State:	Zip:
Home Phone: ( )	Cell/Work Phone: ( )	Birth Date: MM / DD / YEAR	
Email:		Okay to call patient: ☐Yes/ ☐No	
Primary Insurance (PI) Name:		PI Phone: ( )	
☐**Commercial** ☐**Medicare/Medicaid** ☐**Pending Medicaid** ☐**No Insurance** PI Subscriber ID:			
PI Subscriber Name:	PI Subscriber Birth Date: MM / DD / YEAR	Policy/Group ID #:	
Secondary Insurance (SI) Name:		SI Phone: ( )	
☐**Commercial** ☐**Medicare/Medicaid** ☐**Pending Medicaid** ☐**No Insurance** SI Subscriber ID:			
SI Subscriber Name:	SI Subscriber Birth Date: MM / DD / YEAR	Policy/Group ID #:	

HEALTHCARE PROVIDER INFORMATION			
Healthcare Provider Name:		Clinic Name (if applicable):	
Address:		City:	State: Zip:
Contact Name:	Phone: ( )	Fax: ( )	
Do you prefer to be the sole point of contact? ☐Yes ☐No	DEA #:	Tax ID #: NPI #:	Fax: ( ) (for additional summary of benefits)

SITE OF ADMINISTRATION ☐ **Same as above**

(IF FAX NUMBER IS PROVIDED, A COPY OF PATIENT'S SUMMARY OF BENEFITS WILL BE SENT TO THE SITE OF ADMINISTRATION)

Facility Name:		Contact Name:	
Address:		City:	State: Zip:
Phone: ( )	Fax: ( )	Site Tax ID #:	Site NPI #:

TREATMENT INFORMATION

Ulcerative Colitis	**Crohn's Disease**	Has patient started therapy? ☐Yes ☐No If yes, last treatment date: MM / DD / YEAR
ICD-9 code:_____	ICD-9 code:_____	Prior biologic therapy? ☐Yes ☐No
OR	OR	Please list most recent therapy and date/duration:
ICD-10 code:_____	ICD-10 code:_____	

PRESCRIPTION (REQUIRED FOR SPECIALTY PHARMACY BENEFIT)

Initiation: Entyvio 300 mg IV Dispense: ☐Qty: _____vial(s) Refill_____times **Dosage and Directions for Use:** ☐300 mg IV infusion at Week(s) _____ ☐Other_____	Continuing: Entyvio 300 mg IV Dispense: ☐Qty: _____vial(s) Refill_____times **Dosage and Directions for Use:** ☐300 mg IV infusion at Week(s) _____ ☐Other_____

Do you intend to buy & bill? ☐Yes ☐No

If no, please provide preferred specialty pharmacy _____ and phone number (if any): ( )

PRESCRIPTION AUTHORIZATION/CERTIFICATION OF MEDICAL NECESSITY/AUTHORIZATION TO RELEASE PATIENT INFORMATION

By signing this form, you are certifying that a) you authorize Takeda Pharmaceuticals America, Inc. and its agents or contractors to forward the above statement of medical necessity and furnish any information on this form to the insurer of the above-named patient and b) the described therapy above is medically necessary and c) you have received from the patient identified above, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state privacy laws and regulations, referenced medical and/or other patient information relating to the need for Entyvio therapy to Takeda Pharmaceuticals America, Inc. and its agents or contractors for the purpose of seeking information related to coverage for Entyvio therapy and/or assisting in initiating or continuing Entyvio therapy.

Prescriber Signature:	Date:

In New York, please attach copies of all prescriptions on Official New York State Prescription forms.

Please fax the signed form to 1-877-488-6814. For questions, please call *Entyvio Connect* at 1-855-ENTYVIO (1-855-368-9846), Monday to Friday, from 8 AM to 8 PM EST (except holidays).

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.

Takeda

2 PATIENT AUTHORIZATION AND CO-PAY CONSENT FORM

Entyvio CONNECT | Entyvio® vedolizumab

PATIENT AUTHORIZATION AND CO-PAY CONSENT FORM FOR *ENTYVIO CONNECT*

Entyvio Connect can provide certain support to you and on your behalf during the search for Entyvio therapy reimbursement and support programs including co-pay assistance. The *Entyvio Connect* program is an agent of Takeda Pharmaceuticals America, Inc. In order to provide this support, *Entyvio Connect* will need to use your health information (called "Protected Health Information" or "PHI"), and to share it with your health plan and the pharmacy that will receive your doctor's prescription. This authorization will allow your healthcare providers, health plans, and health insurers that maintain PHI about you to disclose your PHI to *Entyvio Connect* so that *Entyvio Connect* may provide this support to you, or on your behalf.

PATIENT AUTHORIZATION AND RELEASE TO COLLECT, USE, AND DISCLOSE MEDICAL INFORMATION

By signing this Authorization, I authorize my physician, health plans and pharmacy providers 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 and any prescription, to *Entyvio Connect* and its representatives, agents, and contractors for the following purposes: (1) to assist me in my health plan coverage for Entyvio, as well as to determine my eligibility for co-pay assistance; (2) to communicate with my healthcare providers and me about my medical care; (3) to facilitate the provision of products, supplies or services by a third party including, but not limited to specialty pharmacies; and (4) to register me in any applicable product registration program required for my treatment.

By checking the box below, I also authorize Takeda Pharmaceuticals America, Inc., its affiliates, and business partners to use my personal information to provide me with information and offers related to Entyvio, the diseases and conditions it treats, and related treatment options.

☐ I consent to receive product and disease-state information from Takeda Pharmaceuticals America, Inc., its affiliates, service providers, and co-promotion partners. I consent to be contacted through the following means (Please check the boxes that apply and fill in your information. You can check more than one box.):

☐ Email: _____ ☐ Postal Mail, at the address below.

I understand that my PHI disclosed under this Authorization may no longer be protected by federal privacy law and may be re-disclosed by *Entyvio Connect.* I understand that I may refuse to sign this Authorization and that my treatment, payment, enrollment or eligibility for benefits is not conditioned on my signing this Authorization. I understand that I am entitled to a copy of this Authorization. I understand that I may cancel this Authorization at any time by mailing a letter requesting such cancellation to *Entyvio Connect*, PO Box 29219, Phoenix, AZ 85038-9219, but that this cancellation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from today's date, unless a shorter period is provided for by state law.

Signature:		Date:
Address:		
Patient's Printed Name:	Phone: ( )	☐ OK to leave a message at this number.

Please fax the signed form to 1-877-488-6814. For questions, please call *Entyvio Connect* at 1-855-ENTYVIO (1-855-368-9846), Monday to Friday, from 8 AM to 8 PM EST (except holidays).

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DIAGNOSIS CODES QUICK REFERENCE GUIDE

This guide is designed to support the reimbursement process for both providers and payers by providing coding information for Entyvio (vedolizumab). Providers are responsible for determining and submitting the appropriate codes, charges, and modifiers for all medically appropriate services and products. Please contact individual payers for current and specific coding, coverage, and payment policies.

The following ICD-9-CM or ICD-10-CM diagnosis codes may be appropriate to describe these disease states:

ULCERATIVE COLITIS (UC) ICD-9 TO ICD-10 CONVERSION TABLE[1]

ICD-9 diagnosis codes			ICD-10 diagnosis codes	
Code	**Description**		**Code**	**Description**
556.0	Ulcerative (chronic) enterocolitis	→	K51.80	Other ulcerative colitis without complications
556.1	Ulcerative (chronic) ileocolitis	→	K51.80	Other ulcerative colitis without complications
556.2	Ulcerative (chronic) proctitis	→	K51.20	Ulcerative (chronic) proctitis without complications
556.3	Ulcerative (chronic) proctosigmoiditis	→	K51.30	Ulcerative (chronic) rectosigmoiditis without complications
556.5	Left-sided ulcerative (chronic) colitis	→	K51.50	Left-sided colitis without complications
556.6	Universal ulcerative (chronic) colitis	→	K51.00	Ulcerative (chronic) pancolitis without complications
556.8	Other ulcerative colitis	→	K51.80	Other ulcerative colitis without complications
556.9	Ulcerative colitis, unspecified	→	K51.90	Ulcerative colitis, unspecified, without complications

CROHN'S DISEASE (CD) ICD-9 TO ICD-10 CONVERSION TABLE[1]

ICD-9 diagnosis codes			ICD-10 diagnosis codes	
Code	**Description**		**Code**	**Description**
555.0	Regional enteritis of small intestine	→	K50.00	Crohn's disease of small intestine without complications
555.1	Regional enteritis of large intestine	→	K50.10	Crohn's disease of large intestine without complications
555.2	Regional enteritis of small intestine with large intestine	→	K50.80	Crohn's disease of both small and large intestine without complications
555.9	Regional enteritis of unspecified site	→	K50.90	Crohn's disease, unspecified, without complications

Please see Indications and Important Safety Information on page 4.

Reference: 1. AAPC. ICD-10 Code Translator. https://www.aapc.com/icd-10/codes. Accessed September 8, 2015.

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 to read the full Prescribing Information, including Medication Guide.