1 BENEFIT INVESTIGATION ENROLLMENT FORM

EntyvioCONNECT | 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 *EntyvioConnect* 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.

2 PATIENT AUTHORIZATION AND CO-PAY CONSENT FORM

EntyvioCONNECT | Entyvio® vedolizumab

PATIENT AUTHORIZATION AND CO-PAY CONSENT FORM FOR *ENTYVIOCONNECT*

EntyvioConnect 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 *EntyvioConnect* program is an agent of Takeda Pharmaceuticals America, Inc. In order to provide this support, *EntyvioConnect* 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 *EntyvioConnect* so that *EntyvioConnect* may provide this support to you, or on your behalf.

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

By signing below, I authorize my physician, health insurance, and pharmacy providers to disclose my personal 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 ("Personal Health Information"), to Takeda Pharmaceuticals U.S.A., Inc., 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 Personal 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 support, financial assistance with co-pays, patient assistance programs, alternate funding sources, and other related programs. I understand that employees of the Companies only see my Personal Health Information in connection with administering the *EntyvioConnect* Patient Support Program or as otherwise required or allowed under the law. I understand that they will make every effort to keep my information private, but if it is accidentally shared with an associated party, my Personal 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. 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 today's date, 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.

☐ Check this box to confirm that you understand that *EntyvioConnect* Patient Support Program is a Takeda sponsored coordination-of-care program designed to provide personalized treatment support. By checking this box, you understand that Takeda and its business partners will need to use your personal information, to enroll you in the program and provide the support you are asking for. Additionally, you authorize Takeda, its affiliates and business partners to use your personal information to provide you with information and offers related to ENTYVIO, disease and the conditions it treats, and related treatment options. In addition to information about ENTYVIO and related health conditions, you understand this may include information from Takeda, financial assistance programs, clinical trials and market research opportunities, and other support services or programs Takeda may in the future develop for patients.

You may revoke your permission at any time. To learn how Takeda will use and protect your personal information please review our Privacy Policy at http://www.takeda.us/home/privacy_policy.aspx

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 *EntyvioConnect* 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.