Entyvio

Prior Authorization Request

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Please indicate the place of service for the requested drug:
❑ *Ambulatory Surgical* ❑ *Home* ❑ *Inpatient Hospital* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

Exception Criteria Questions:

A. These are the preferred products for which coverage is provided for treatment of the following conditions:
- Rheumatoid arthritis, psoriatic arthritis: **Orencia, Remicade, and Simponi Aria**
- Plaque psoriasis, Crohn's disease, ulcerative colitis: **Remicade**
- Ankylosing spondylitis: **Remicade and Simponi Aria**
- Polyarticular juvenile idiopathic arthritis: **Orencia**

Can the patient's treatment be switched to a preferred product?
❑ Yes, *Please obtain Form for preferred product and submit for corresponding PA.*
❑ No

B. Is this request for continuation of therapy with the requested product? ❑ Yes ❑ No, *skip to Question D*

C. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes.
❑ Yes ❑ No, *skip to Clinical Criteria Questions*

D. What is the diagnosis?
❑ Rheumatoid Arthritis
❑ Plaque psoriasis, *skip to Question F.*
❑ Crohn's disease, *skip to Question F.*
❑ Ulcerative colitis, *skip to Question F.*
❑ Psoriatic arthritis
❑ Ankylosing spondylitis, *skip to Question I.*
❑ Polyarticular juvenile idiopathic arthritis, *skip to Question H.*
❑ Other, *skip to Clinical Criteria Questions*

E. Has the patient had a documented inadequate response or intolerable adverse event with all of the preferred products (Orencia, Remicade, or Simponi Aria)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No, *skip to Clinical Criteria Questions*

F. Has the patient had a documented inadequate response or intolerable adverse event with the preferred product (Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Does the patient have one of the following documented clinical reasons to avoid Remicade? *Indicate below and skip to Clinical Criteria Questions.* **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes – History of demyelinating disorder
❑ Yes – History of congestive heart failure
❑ Yes – History of hepatitis B virus infection
❑ Yes – Autoantibody formation/lupus-like syndrome
❑ Yes – Risk of lymphoma
❑ No

H. Has the patient had a documented inadequate response or intolerable adverse event with the preferred product (Orencia)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No, *skip to Clinical Criteria Questions*

I. Has the patient had a documented inadequate response or intolerable adverse event with all preferred products (Remicade or Simponi Aria)? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

Site of Service Questions (SOS):

A. Indicate the site of service requested:
❑ On Campus Outpatient Hospital
❑ Off Campus Outpatient Hospital
❑ Physician office, *skip to Clinical Questions*
❑ Home infusion, *skip to Clinical Questions*
❑ Pharmacy, *skip to Clinical Questions*
❑ Ambulatory surgical, *skip to Clinical Questions*
❑ Inpatient hospital, *skip to Clinical Questions*

B. Is the patient less than 21 years old or 65 years of age or older?
❑ Yes – less than 21 years old
❑ Yes – age 65 years or older, *skip to Clinical Criteria Questions*
❑ No, *Skip to Question D.*

C. After tolerance of the medication has been established, would this patient be a candidate to receive Ig therapy in a setting other than the hospital? *Indicate and skip to Clinical Criteria Questions* ❑ Yes ❑ No

D. Is this request to continue previously established treatment with the requested medication?
❑ Yes ❑ No, *skip to Clinical Criteria Questions*

E. Has the patient experienced moderate to severe adverse reactions with the requested medication use that have not responded to conventional interventions e.g. acetaminophen, steroids, diphenhydramine, fluids or other pre-medications? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Does the patient have laboratory confirmed autoantibodies to the requested medication? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Has the patient previously experienced a severe adverse event during or immediately after an infusion including but not limited to: anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

I. Does the patient have severe venous access issues that require the use of a special intervention? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

J. Has the patient's home been previously determined to be inappropriate for home infusion by a social worker, case manager, or previous home care nurse assessment AND other non-hospital sites of service are not within a reasonable distance from the patient's home? ***ACTION REQUIRED: Attach supporting clinical documentation.*** *Indicate and continue to Clinical Criteria Questions* ❑ Yes ❑ No

Criteria Questions:

1. Has the patient been diagnosed with any of the following?
❑ Moderately to severely active Crohn's disease (CD) ❑ Moderately to severely active ulcerative colitis (UC)
❑ Other _____

2. What is the ICD-10 code? _____

3. Is the patient currently receiving Entyvio? ❑ Yes ❑ No

4. Is this request for continuation of therapy? ❑ Yes ❑ No *If No, skip to #8*

5. Is the patient currently receiving Entyvio through samples or a manufacturer's patient assistance program?
❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #8*

6. How long has the patient been receiving the requested medication? _____ months
If less than 4 months, no further questions.

7. Has the patient achieved or maintained positive clinical response to treatment as evidenced by low disease activity or improvement in signs and symptoms? *If Yes, no further questions* ❑ Yes ❑ No

8. Has the patient received any of the following medications?
If Yes, please indicate the most recent medication and skip to diagnosis section.
❑ Cimzia ❑ Humira ❑ Inflectra ❑ Remicade ❑ Renflexis ❑ Simponi ❑ Stelara ❑ Tysabri ❑ No

9. Has the patient undergone pretreatment screening for latent tuberculosis (TB) infection with either a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB)? ❑ Yes ❑ No

Section A: Crohn's Disease

10. Has the patient tried and had an inadequate response to at least one conventional therapy option?
    If Yes, indicate below and no further questions.
    - ❑ Yes - Sulfasalazine (Azulfidine, Sulfazine)
    - ❑ Yes - Mesalamine, oral (Asacol, Pentasa, Delzicol, Lialda)
    - ❑ Yes - Metronidazole (Flagyl)
    - ❑ Yes - Ciprofloxacin (Cipro)
    - ❑ Yes - Prednisone
    - ❑ Yes - Budesonide (Entocort EC)
    - ❑ Yes - Azathioprine (Azasan, Imuran)
    - ❑ Yes - Mercaptopurine (Purinethol)
    - ❑ Yes - Methotrexate
    - ❑ Yes - Methylprednisolone (Solu-Medrol)
    - ❑ Yes - Rifaximin (Xifaxan)
    - ❑ No

11. Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], budesonide [Entocort EC], ciprofloxacin [Cipro], mesalamine [Asacol, Delzicol, Lialda, Pentasa], mercaptopurine [Purinethol], methylprednisolone [Solu-Medrol], methotrexate, metronidazole [Flagyl], prednisone, sulfasalazine [Azulfidine, Sulfazine], rifaximin [Xifaxan])?
    If Yes, no further questions ❑ Yes ❑ No

12. Has the patient had an inadequate response to a TNF-alpha inhibitor indicated for the treatment of CD (e.g., Cimzia, Humira, Remicade)? *If Yes, no further questions* ❑ Yes ❑ No

13. Does the patient have a contraindication or intolerance to a TNF-alpha inhibitor indicated for the treatment of CD (e.g., Cimzia, Humira, Remicade)? ❑ Yes ❑ No

Section B: Ulcerative Colitis

14. Has the patient tried and had an inadequate response to at least one conventional therapy option?
    If Yes, indicate below and no further questions.
    - ❑ Yes - Azathioprine (Azasan, Imuran)
    - ❑ Yes - Corticosteroid (e.g., budesonide [Entocort, Uceris], hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone)
    - ❑ Yes - Cyclosporine (Sandimmune)
    - ❑ Yes - Mesalamine (e.g., Asacol, Lialda, Pentasa, Canasa, Rowasa)
    - ❑ Yes - Mercaptopurine (Purinethol)
    - ❑ Yes - Sulfasalazine
    - ❑ Yes - Tacrolimus (Prograf)
    - ❑ Yes - Metronidazole (Flagyl) or Ciprofloxacin (Cipro) (for pouchitis only)
    - ❑ No

15. Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], corticosteroid [e.g., budesonide [Entocort, Uceris], hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone], cyclosporine [Sandimmune], mesalamine [Asacol, Lialda, Pentasa, Canasa, Rowasa], mercaptopurine [Purinethol], sulfasalazine, tacrolimus [Prograf], metronidazole/ciprofloxacin [for pouchitis only])? *If Yes, no further questions* ❑ Yes ❑ No

16. Has the patient had an inadequate response to a TNF-alpha inhibitor indicated for the treatment of UC (e.g., Humira, Remicade, Simponi)? *If Yes, no further questions* ❑ Yes ❑ No

17. Does the patient have a contraindication or intolerance to a TNF-alpha inhibitor indicated for the treatment of UC (e.g., Humira, Remicade, Simponi)? ❑ Yes ❑ No

Step Therapy Override: Complete if Applicable.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**