Inflectra

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.

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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

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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. What is the diagnosis?
☐ Rhematoid Arthritis
☐ Crohn's disease
☐ Psoriatic arthritis
☐ Polyarticular juvenile idiopathic arthritis
☐ Other, *skip to Site Of Service Questions*
☐ Plaque psoriasis
☐ Ulcerative colitis
☐ Ankylosing spondylitis

C. Has the patient experienced a documented intolerable adverse event with the preferred product (Remicade)?
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
☐ Home infusion, *skip to Clinical Questions*
☐ Ambulatory surgical, *skip to Clinical Questions*
☐ Off Campus Outpatient Hospital
☐ Physician office, *skip to Clinical Questions*
☐ Pharmacy, *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 Remicade, Inflectra or Renflexis has been established, would this patient be a candidate to receive the medication at a site of service other than the outpatient hospital setting?
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 a gap in therapy exceeding 2 infusions or more and the current request is a re-initiation of therapy? ☐ Yes, *skip to Clinical Criteria Questions* ☐ No

F. Does the patient have laboratory confirmed anti- Remicade, anti- Inflectra or anti-Renflexis antibodies?
ACTION REQUIRED: Attach supporting clinical documentation. ☐ Yes, *skip to Clinical Criteria Questions* ☐ No

G. Has the patient experienced moderate to severe adverse reactions which may include hypertension or hypotension, tachycardia or syncope that have not responded to conventional interventions? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ☐ Yes, *skip to Clinical Criteria Questions* ☐ No

H. 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

I. 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

J. 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

K. 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 (physician office, pharmacy, ambulatory surgical, and inpatient hospital) are not within a reasonable distance from the patient's home? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ☐ Yes ☐ No

Criteria Questions:

1. What is the prescribed drug? ☐ Inflectra ☐ Renflexis

2. 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)
   ☐ Moderately to severely active rheumatoid arthritis (RA)
   ☐ Active ankylosing spondylitis
   ☐ Active axial spondyloarthritis
   ☐ Active psoriatic arthritis (PsA)
   ☐ Chronic and severe plaque psoriasis
   ☐ Juvenile idiopathic arthritis (JIA)
   ☐ Behçet's syndrome
   ☐ Granulomatosis with polyangiitis (Wegener's granulomatosis)
   ☐ Severe, refractory hidradenitis suppurativa
   ☐ Pyoderma gangrenosum
   ☐ Sarcoidosis
   ☐ Takayasu's arteritis
   ☐ Uveitis
   ☐ Other ____

3. What is the ICD-10 code? ________________ *If diagnosis is hidradenitis suppurativa, no further questions.*

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

5. Is the patient currently receiving Remicade, Inflectra or Renflexis through samples or a manufacturer's patient assistance program?
   ☐ Yes - Remicade ☐ Yes - Inflectra ☐ Yes - Renflexis ☐ No ☐ Unknown *If Yes or Unknown, skip to #8*

6. How long has the patient been receiving the requested medication? _______________ months
   For RA requests: *If less than 3 months, skip to diagnosis section.*
   For all other requests: *If less than 3 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? ☐ Yes ☐ No
   For RA requests: *If Yes, skip to diagnosis section.*
   For all other requests: *If Yes, no further questions.*

8. Has the patient received any of the following medications?
   If Yes, please indicate the most recent medication and skip to diagnosis section.
   ☐ Actemra ☐ Cimzia ☐ Cosentyx ☐ Enbrel ☐ Entyvio ☐ Humira ☐ Inflectra ☐ Kevzara ☐ Kineret
   ☐ Orencia ☐ Remicade ☐ Renflexis ☐ Rituxan ☐ Siliq ☐ Simponi ☐ Simponi Aria ☐ Stelara ☐ Taltz
   ☐ Tremfya ☐ Xeljanz ☐ Xeljanz XR ☐ 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

Complete the following section based on the patient's diagnosis, if applicable

Section A: Crohn’s Disease

10. Does the patient have fistulizing disease? *If Yes, no further questions* ☐ Yes ☐ No

11. 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

12. 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, Pentasa, Lialda], mercaptopurine [Purinethol], methylprednisolone [Solu-Medrol], methotrexate, metronidazole [Flagyl], prednisone, sulfasalazine [Azulfidine, Sulfazine], rifaximin [Xifaxan])? ☐ Yes ☐ No

Section B: Ulcerative Colitis

13. 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

14. Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], corticosteroid [e.g., budesonide, hydrocortisone, methylprednisolone, prednisone], cyclosporine [Sandimmune], mesalamine [Asacol, Lialda, Pentasa, Canasa, Rowasa], mercaptopurine [Purinethol], sulfasalazine, tacrolimus, metronidazole/ciprofloxacin [for pouchitis only])? ☐ Yes ☐ No

Section C: Rheumatoid Arthritis

15. Is the requested medication being prescribed in combination with methotrexate or leflunomide? ☐ Yes ☐ No
    If No, indicate clinical reason for not using methotrexate or leflunomide:
    ____

16. Has the patient experienced an inadequate response after at least 3 months of treatment with the methotrexate dose greater than or equal to 20 mg per week? *If Yes, no furher questions* ☐ Yes ☐ No

17. Has the patient experienced intolerance to methotrexate? *If Yes, no further questions* ☐ Yes ☐ No

18. Does the patient have a contraindication to methotrexate? ☐ Yes ☐ No
    If Yes, indicate the contraindication: ____

Section D: Ankylosing Spondylitis or Axial Spondyloarthritis

19. Has the patient experienced an inadequate response with at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs), or has an intolerance or contraindication to at least two NSAIDs? ☐ Yes ☐ No

Section E: Plaque Psoriasis

20. What is the percentage of body surface area (BSA) affected? _______________ %

21. *If less than 5% of BSA affected,* are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? ☐ Yes ☐ No

22. Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin? *If Yes, no further questions* ☐ Yes ☐ No

23. Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin? ☐ Yes ☐ No ***If Yes, indicate the clinical reason:*** ____

24. Does the patient have severe psoriasis that warrants a biologic DMARD as first-line therapy? ☐ Yes ☐ No

Section F: Juvenile Idiopathic Arthritis

25. Has the patient received treatment with a self-injectable TNF inhibitor indicated for idiopathic arthritis (JIA) (e.g., Enbrel or Humira)?
    ☐ Yes – Enbrel ☐ Yes – Humira ☐ Yes – Both Enbrel and Humira ☐ Other ____________________________

26. Has the patient experienced any of the following during treatment with Enbrel or Humira?
    ☐ Yes – Inadequate response to at least a 3-month trial
    ☐ Yes – Development of antibodies
    ☐ Yes – Intolerable adverse event (e.g., hypersensitivity reaction)
    ☐ No

Section G: Uveitis

27. Has the patient had an inadequate response or intolerance, or has a contraindication to a trial of immunosuppressive therapy for uveitis (e.g., methotrexate, azathioprine, or mycophenolate mofetil)?
    ☐ Yes – methotrexate
    ☐ Yes – azathioprine
    ☐ Yes – mycophenolate mofetil
    ☐ Yes – other _____________________________________
    ☐ 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____