Remicade and biosimilars

Prior Authorization Request

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 **1-888-877-0518.** 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*

Exception Criteria Questions:

A. Is the product being requested for the treatment of an ADULT patient (18 years of age or older) with one of the following indications?
   - Ankylosing spondylitis
   - Crohn's disease
   - Plaque psoriasis
   - Psoriatic arthritis
   - Rheumatoid arthritis
   - Ulcerative colitis

   ❑ Yes ❑ No *If No, skip to Site of Service Questions*

B. These are the preferred products for which coverage is provided for treatment of the following indications:
   - Ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis: **Remicade and Simponi Aria**
   - Plaque psoriasis: **Ilumya and Remicade**
   - Crohn's disease, ulcerative colitis: **Entyvio and Remicade**
   - **Stelara IV** is indicated for a one time induction dose for Crohn's disease and ulcerative colitis.

Can the patient's treatment be switched to a preferred product?
❑ Yes, *Please obtain Form for preferred product and submit for corresponding PA. If switching to Remicade, Skip to Site of Service Questions*
❑ No

C. Does the patient have a documented intolerable adverse event to the preferred product, Remicade? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

D. Was the documented intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information? ❑ Yes ❑ No

E. What is the diagnosis?
❑ Ankylosing spondylitis
❑ Crohn's disease, *skip to Question G*
❑ Plaque Psoriasis, *skip to Question H*
❑ Psoriatic arthritis
❑ Ulcerative colitis, *skip to Question G*
❑ Rheumatoid arthritis
❑ Other_______________________

F. Does the patient have a documented inadequate response or intolerable adverse event to Simponi Aria? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No *Skip to Site of Service Questions*

G. Does the patient have a documented inadequate response or intolerable adverse event to Entyvio? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No *Skip to Site of Service Questions*

H. Does the patient have a documented inadequate response or intolerable adverse event to Ilumya? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

Site of Service Questions:

A. Where will this drug be administered?
❑ Ambulatory surgical, *skip to Clinical Questions*
❑ Home infusion, *skip to Clinical Questions*
❑ Off-campus Outpatient Hospital
❑ On-campus Outpatient Hospital
❑ Physician office, *skip to Clinical Questions*
❑ Pharmacy, *skip to Clinical Questions*

B. Is this request to continue previously established treatment with the requested medication?
❑ Yes – This is a continuation of an existing treatment
❑ Yes – This is a continuation request, however a gap in therapy of greater than 2 doses has occurred. *Skip to Clinical Criteria Questions*
❑ No – This is a new therapy request (patient has not received requested medication in the last 6 months). *Skip to Clinical Criteria Questions*
❑ No – This is a request for a different brand infliximab product that the patient has not received previously. *Skip to Clinical Criteria Questions*

C. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre- medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

D. Does the patient have laboratory confirmed antibodies to infliximab? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

E. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Does the patient have severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation. ❑ Yes ❑ No

Criteria Questions:

1. What is the prescribed drug? ❑ Remicade ❑ Avsola ❑ Inflectra ❑ Renflexis

2. What is the prescribed dose and frequency?
   a) **Loading dose:**
   ❑ Remicade 100 mg Quantity and Frequency: ______
   ❑ Avsola 100 mg Quantity and Frequency: ______
   ❑ Inflectra 100 mg Quantity and Frequency: ______
   ❑ Renflexis 100 mg Quantity and Frequency: ______
   ❑ Other ______________

   b) **Maintenance dose:**
   ❑ Remicade 100 mg Quantity and Frequency: ______
   ❑ Avsola 100 mg Quantity and Frequency: ______
   ❑ Inflectra 100 mg Quantity and Frequency: ______
   ❑ Renflexis 100 mg Quantity and Frequency: ______
   ❑ Other ______________

   c) **Dosing (other):** *Indicate all that apply.*
   ❑ This is a request for a change in dosing regimen.
   ❑ The requested quantity is supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines.
   ❑ The patient requires a dose above 5 mg per kg due to loss of response at current dose.
   ❑ The patient requires a dose above 3 mg per kg due to an incomplete response at current dose.

3. Has the patient been diagnosed with any of the following? *List continues on next page.*
   ❑ 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 (AS)
   ❑ Active axial spondyloarthritis
   ❑ Active psoriatic arthritis WITHOUT co-existent plaque psoriasis (PsA)
   ❑ Active psoriatic arthritis with co-existent plaque psoriasis (PsA)
   ❑ Moderate to severe plaque psoriasis
   ❑ Juvenile idiopathic arthritis
   ❑ Behcet's disease
   ❑ Granulomatosis with polyangiitis (Wegener's granulomatosis)
   ❑ Severe, refractory hidradenitis suppurativa
   ❑ Pyoderma gangrenosum
   ❑ Sarcoidosis
   ❑ Refractory Takayasu's arteritis
   ❑ Uveitis
   ❑ Reactive arthritis
   ❑ Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity
   ❑ Acute graft versus host disease
   ❑ Other ____

4. What is the ICD-10 code? ____________________

5. What is the patient's weight?_kg or lbs ***(circle one)***

6. Is the patient currently receiving Remicade or a biosimilar? ❑ Yes ❑ No

Section A: All Requests

7. Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic disease-modifying anti-rheumatic drug (DMARD) (e.g., Olumiant, Otezla, Xeljanz)?
   ❑ Yes ❑ No

8. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis (TB)?
   If Yes, skip to #10 ❑ Yes ❑ No

9. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [PPD], interferon-release assay [IGRA], chest x-ray) within 6 months of initiating therapy? *If Yes, skip to #12* ❑ Yes ❑ No

10. Does the patient have risk factors for tuberculosis (TB) (e.g., persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB [e.g., Africa, Asia, Eastern Europe, Latin America, Russia]; children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission [e.g., homeless persons, injection drug users, persons with HIV infection], or persons who work or reside with people who are at an increased risk for active TB [e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters])? ❑ Yes ❑ No *If No, skip to #15*

11. Has the patient been tested for tuberculosis (TB) within the previous 12 months? ❑ Yes ❑ No

12. What were the results of the tuberculosis (TB) test?
    ❑ Positive for TB ❑ Negative for TB, *skip to #15* ❑ Unknown

13. Does the patient have latent or active tuberculosis (TB)? ❑ Latent ❑ Active ❑ Unknown

14. Has treatment for latent tuberculosis (TB) infection been initiated or completed?
    ❑ Yes - treatment initiated ❑ Yes - treatment completed ❑ No

15. Is this request for continuation of therapy with the requested drug or a biosimilar?
    ❑ Yes ❑ No *If No, skip to #18*

16. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #18* ❑ Yes ❑ No ❑ Unknown

17. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?
    ❑ Yes ❑ No

18. Has the patient ever received (including current utilizers) any of the following? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried.***
    ❑ A biologic (e.g., Humira, Cimzia, Enbrel) indicated for the diagnosis, *indicate biologic:* ________
    ❑ Targeted synthetic disease modifying drug (e.g., Rinvoq, Xeljanz) indicated for the diagnosis
    ❑ Otezla
    ❑ No - None of the above

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

Section B: Crohn's Disease

19. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of remission and no further questions.*** ❑ Yes ❑ No

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Remicade and biosimilars MR SOC SGM – 08/2021.

Continuation

20. Which of the following has the patient experienced an improvement in from baseline***? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy and no further questions.***
    - ❑ Abdominal pain or tenderness
    - ❑ Diarrhea
    - ❑ Body weight
    - ❑ Abdominal mass
    - ❑ Hematocrit
    - ❑ Endoscopic appearance of the mucosa
    - ❑ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)
    - ❑ None of the above

Initiation

21. Does the patient have fistulizing disease? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting diagnosis. and no further questions.*** ❑ Yes ❑ No

22. Has the patient tried and had an inadequate response to at least one conventional therapy option? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.***
    - ❑ Yes - Sulfasalazine (Azulfidine, Sulfazine) ❑ Yes - Budesonide (Entocort EC)
    - ❑ Yes - Mercaptopurine (Purinethol) ❑ Yes - Azathioprine (Azasan, Imuran)
    - ❑ Yes - Metronidazole (Flagyl) ❑ Yes - Methotrexate IM or SC
    - ❑ Yes - Ciprofloxacin (Cipro) ❑ Yes - Methylprednisolone (Solu-Medrol)
    - ❑ Yes - Prednisone ❑ Yes - Rifaximin (Xifaxan)
    - ❑ Yes - Tacrolimus ❑ No

23. 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], mercaptopurine [Purinethol], methylprednisolone [Solu-Medrol], methotrexate IM or SC, metronidazole [Flagyl], prednisone, sulfasalazine [Azulfidine, Sulfazine], rifaximin [Xifaxan], tacrolimus)? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section C: Ulcerative Colitis

Continuation

24. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of remission and no further questions.*** ❑ Yes ❑ No

25. Which of the following has the patient experienced an improvement in from baseline***? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy and no further questions.***
    - ❑ Stool frequency
    - ❑ Rectal bleeding
    - ❑ Urgency of defecation
    - ❑ C-reactive protein (CRP)
    - ❑ Fecal calprotectin (FC)
    - ❑ Endoscopic appearance of the mucosa
    - ❑ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score])
    - ❑ None of the above

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Remicade and biosimilars MR SOC SGM – 08/2021.

Initiation

9. Has the patient been hospitalized for fulminant ulcerative colitis (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia)? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of hospitalization and no further questions.*** ❑ Yes ❑ No

10. Has the patient tried and had an inadequate response to at least one conventional therapy option? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy 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., Apriso, Asacol, Lialda, Pentasa, Canasa, Rowasa), balsalazide, or olsalazine
    ❑ Yes - Mercaptopurine (Purinethol)
    ❑ Yes - Sulfasalazine
    ❑ Yes - Tacrolimus (Prograf)
    ❑ Yes - Metronidazole (Flagyl) or ciprofloxacin (Cipro) (for pouchitis only)
    ❑ No

11. 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, methylprednisolone, prednisone], cyclosporine [Sandimmune], mesalamine [Asacol, Lialda, Pentasa, Canasa, Rowasa], balsalazide, olsalazine, mercaptopurine [Purinethol], sulfasalazine, tacrolimus [Prograf], metronidazole/ciprofloxacin [for pouchitis only])? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including clinical reason to avoid therapy***. ❑ Yes ❑ No

Section D: Rheumatoid Arthritis and Reactive Arthritis

Continuation

12. *If the diagnosis is rheumatoid arthritis,* has the patient achieved or maintained positive clinical response since starting treatment with the requested drug? ❑ Yes ❑ No

13. *If diagnosis is reactive arthritis*, has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, or pain)? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation supporting positive clinical response and no further questions.*** ❑ Yes ❑ No

14. What is the percent of disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.*** ________%
    No further questions.

Initiation – for diagnosis of Reactive Arthritis, skip to #40

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. Does the patient meet BOTH of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker AND b) the RF biomarker test was positive? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing and skip to #40.*** ❑ Yes ❑ No

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Remicade and biosimilars MR SOC SGM – 08/2021.

17. Does the patient meet BOTH of the following: a) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker AND b) the anti-CCP biomarker test was positive? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing and skip to #40.***
❑ Yes ❑ No

18. Has the patient been tested for the rheumatoid factor (RF) biomarker? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

19. Has the patient been tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing.***
❑ Yes ❑ No

20. Has the patient been tested for the C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) biomarker(s)? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

21. Please indicate if the patient tested positive or negative for the C-reactive protein (CRP) biomarker, or if the test was not completed.
❑ Positive for CRP
❑ Negative for CRP
❑ Test for CRP was not completed

22. Please indicate if the patient tested positive or negative for the erythrocyte sedimentation rate (ESR) biomarker, or if the test was not completed.
❑ Positive for ESR
❑ Negative for ESR
❑ Test for ESR was not completed

23. Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 20 mg per week? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. Indicate below and no further questions.*** ❑ Yes ❑ No

24. Has the patient experienced an intolerance to methotrexate? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. Indicate below and no further questions.*** ❑ Yes ❑ No

25. Does the patient have a contraindication to methotrexate? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including clinical reason to avoid therapy.*** ❑ Yes ❑ No
If Yes, indicate the contraindication: ____

Section E: Ankylosing Spondylitis or Active Axial Spondyloarthritis

Continuation

26. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy and no further questions.***
❑ Functional status ❑ Inflammation (e.g., morning stiffness)
❑ Total spinal pain ❑ None of the above

Initiation

27. 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? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Remicade and biosimilars MR SOC SGM – 08/2021.

Section F: Psoriatic Arthritis

Continuation

28. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response***.
    - ❑ Number of swollen joints
    - ❑ Number of tender joints
    - ❑ Dactylitis
    - ❑ Enthesitis
    - ❑ Skin and/or nail involvement
    - ❑ None of the above

Section G: Plaque Psoriasis

Continuation

29. Has the patient experienced a reduction in body surface area (BSA) affected from baseline? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of decreased body surface area affected.*** ❑ Yes ❑ No

30. Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of improvement in signs and symptoms.*** ❑ Yes ❑ No

Initiation

31. Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of affected areas and body surface area affected.*** ❑ Yes ❑ No

32. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? ***ACTION REQUIRED: Please attach chart notes or medical record documentation of affected areas and body surface area affected.*** __________% *If greater than or equal to 10% of BSA, no further questions.*

33. 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? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

34. Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin? ***ACTION REQUIRED: If 'Yes', please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No
    If Yes, indicate the clinical reason: ____

Section H: Juvenile Idiopathic Arthritis

Continuation

35. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.***
    - ❑ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
    - ❑ Number of joints with limitation of movement
    - ❑ Functional ability
    - ❑ None of the above

Initiation

36. Has the patient experienced an inadequate response to ANY of the following? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.***
    Indicate below and no further questions.
    - ❑ At least 1 month trial of NSAIDs

❑ At least 2 weeks of treatment with corticosteroids (e.g. prednisone, methylprednisolone)
❑ At least 3 months of treatment with methotrexate
❑ At least 3 months of treatment with leflunomide
❑ No – No history of an inadequate response to any of the above

Section I: Behcet's Disease

37. Has the patient had an inadequate response to at least one nonbiologic medication for Behcet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine)? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy*** ❑ Yes ❑ No

Section J: Granulomatosis with Polyangiitis (Wegener's Granulomatosis), Pyoderma Gangrenosum, Sarcoidosis. and Takayasu's Arteritis

38. Has the patient experienced ANY of the following with corticosteroids or immunosuppressive therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and documentation of clinical reason to avoid therapy. Indicate ALL that apply.***
❑ Corticosteroids ❑ Inadequate response ❑ Intolerance ❑ Contraindication
❑ Immunosuppressive therapy ❑ Inadequate response ❑ Intolerance ❑ Contraindication
If immunosuppressive therapy, specify therapy: ___________________________
❑ None of the above

Section K: Hidradenitis Suppurativa

Continuation

39. Which of the following has the patient experienced since starting treatment with the requested drug? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.***
❑ Reduction in abscess and inflammatory nodule count from baseline
❑ Reduced formation of new sinus tracts and scarring
❑ Decrease in frequency of inflammatory lesions from baseline
❑ Reduction in pain from baseline
❑ Reduction in suppuration from baseline
❑ Improvement in frequency of relapses from baseline
❑ Improvement in quality of life from baseline
❑ Improvement on a disease severity assessment tool from baseline
❑ None of the above

Initiation

40. Has the patient experienced an inadequate response after at least 90 days of treatment with oral antibiotics? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** ❑ Yes ❑ No

41. Has the patient experienced an intolerable adverse effect to oral antibiotics? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** ❑ Yes ❑ No

42. Does the patient have a contraindication to oral antibiotics? ACTION REQUIRED: If 'Yes', please attach documentation of clinical reason to avoid therapy. ❑ Yes ❑ No

Section L: Uveitis

Continuation

43. Which of the following has the patient experienced since starting treatment with the requested drug? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response***.
❑ Reduced frequency of recurrence compared to baseline

❑ Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
❑ Decreased reliance on topical corticosteroids
❑ None of the above

Initiation

44. Has the patient experienced ANY of the following with corticosteroids or immunosuppressive therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)? ***Indicate ALL that apply. ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy, or clinical reason to avoid therapy.***
❑ Corticosteroid ❑ Inadequate response ❑ Intolerance ❑ Contraindication
❑ Immunosuppressive therapy ❑ Inadequate response ❑ Intolerance ❑ Contraindication
If immunosuppressive therapy, specify therapy: ______________________
❑ None of the above

Section M: Immune Checkpoint Inhibitor Toxicity

45. Has the patient experienced an inadequate response to corticosteroids? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions***. ❑ Yes ❑ No

46. Has the patient experienced an intolerance to corticosteroids? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions***. ❑ Yes ❑ No

47. Does the patient have a contraindication to corticosteroids? ***ACTION REQUIRED: If 'Yes', please attach documentation of clinical reason to avoid therapy and no further questions.*** ❑ Yes ❑ No

48. Does the patient have cardiac toxicity? ❑ Yes ❑ No

Section N: Acute Graft Versus Host Disease

49. Has the patient experienced an inadequate response to systemic corticosteroids? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions***. ❑ Yes ❑ No

50. Does the patient have an intolerance or contraindication to corticosteroids? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Remicade and biosimilars MR SOC SGM – 08/2021.

Step Therapy Override: Complete if Applicable for the state of Maryland.	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

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical 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)**

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