Cimzia

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*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical*	❑ *Home*	❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital*	❑ *Office*	❑ *Pharmacy*

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

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Exception Criteria Questions:

A. Is the product being requested for the treatment of one of the following indications?
- Ankylosing spondylitis
- Crohn's disease
- Plaque psoriasis
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Rheumatoid arthritis

❑ Yes ❑ No *If No, skip to Clinical Criteria Questions*

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

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

If diagnosis is Plaque psoriasis, skip to Question M

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

D. 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*

E. What is the diagnosis?
❑ Ankylosing spondylitis
❑ Crohn's disease, *skip to Question J*
❑ Psoriatic arthritis
❑ Polyarticular juvenile idiopathic arthritis, *skip to Question P*
❑ Rheumatoid arthritis
❑ Other, *skip to Clinical Criteria Questions*

F. Is the request for an adult patient (18 years of age or older)? ❑ Yes ❑ No *If No, skip to Clinical Criteria Questions*

G. Is the patient currently pregnant or breastfeeding? ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

I. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitor (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).***
❑ Not applicable – Requested medical is a TNF inhibitor, *skip to Clinical Criteria Questions*
❑ Yes – History of demyelinating disorder, *skip to Clinical Criteria Questions*
❑ Yes – History of congestive heart failure, *skip to Clinical Criteria Questions*
❑ Yes – History of hepatitis B virus infection, *skip to Clinical Criteria Questions*
❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor), *skip to Clinical Criteria Questions*
❑ Yes – Risk of lymphoma, *skip to Clinical Criteria Questions*
❑ No – None of the above, *skip to Clinical Criteria Questions*

J. Is the request for an adult patient (18 years of age or older)? ❑ Yes ❑ No *If No, skip to Clinical Criteria Questions*

K. Is the patient currently pregnant or breastfeeding? ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

L. Does the patient have a documented inadequate response or intolerable adverse event to both of the preferred products indicated for Crohn's disease (Entyvio and Stelara IV)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** *If Yes or No, skip to Clinical Criteria Questions* ❑ Yes ❑ No

M. Is the request for an adult patient (18 years of age or older)? ❑ Yes ❑ No *If No, skip to Clinical Criteria Questions*

N. Is the patient currently pregnant or breastfeeding? ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

O. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product indicated for plaque psoriasis (Ilumya)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** *If Yes or No, skip to Clinical Criteria Questions* ❑ Yes ❑ No

P. Is the request for a patient 2 years of age or older? ❑ Yes ❑ No *If No, skip to Clinical Criteria Questions*

Q. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product indicated for polyarticular juvenile idiopathic arthritis (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No *If Yes, skip to Clinical Criteria Questions*

R. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitor (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).***
- ❑ Not applicable – requested medication is a TNF inhibitor
- ❑ Yes – History of demyelinating disorder
- ❑ Yes – History of congestive heart failure
- ❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
- ❑ Yes – Risk of lymphoma
- ❑ No – None of the above

Clinical Criteria Questions:

1. What is the prescribed dose and frequency?

a) **Loading dose:**

❑ Cimzia Starter Kit — Quantity and Frequency: _____
❑ Cimzia 200 mg PFS (prefilled syringe) — Quantity and Frequency: _____
❑ Cimzia Kit (lyophilized powder - vial) — Quantity and Frequency: _____
❑ Other _____

b) **Maintenance dose:**

❑ Cimzia 200 mg PFS (prefilled syringe) — Quantity and Frequency: _____
❑ Cimzia Kit (lyophilized powder - vial) — Quantity and Frequency: _____
❑ Other _____

2. Has the patient been diagnosed with any of the following?
- ❑ Moderately to severely active rheumatoid arthritis (RA)
- ❑ Active psoriatic arthritis WITH co-existent plaque psoriasis (PsA)
- ❑ Active psoriatic arthritis WITHOUT co-existent plaque psoriasis (PsA)
- ❑ Moderately to severely active Crohn's disease (CD)
- ❑ Active ankylosing spondylitis (AS)
- ❑ Active axial spondyloarthritis
- ❑ Moderate to severe plaque psoriasis
- ❑ Other _____

3. What is the ICD-10 code? _____

4. What is the patient's weight?_____kg/lbs ***(circle one)***

Section A: All Requests

5. 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

6. 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? *If Yes, skip to #10*
❑ Yes ❑ No

7. 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? ❑ Yes ❑ No

8. What were the results of the tuberculosis (TB) test?
❑ Positive for TB ❑ Negative for TB, *skip to #10* ❑ Unknown

9. Which of the following applies to the patient?
❑ Patient has latent TB and treatment for latent TB has been initiated
❑ Patient has latent TB and treatment for latent TB has been completed
❑ Patient has latent TB and treatment for latent TB has not been initiated
❑ Patient has active TB

10. Is this request for continuation of therapy with the requested drug?
❑ Yes ❑ No *If No, skip to diagnosis section.*

11. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No ❑ Unknown *If Yes, or unknown, skip to diagnosis section*

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

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

Section B: Rheumatoid Arthritis

Continuation

13. 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 and no further questions.*** _____%

Initiation

14. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medication tried*** *If Yes, no further questions.* ❑ Yes ❑ No

15. Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the biomarker test was positive, or b) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker and 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 #17.***
❑ Yes ❑ No

16. Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)? ***ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

17. Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 15 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 and no further questions.*** ❑ Yes ❑ No

18. 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 and no further questions.*** ❑ Yes ❑ No

19. Does the patient have a contraindication to methotrexate? ❑ Yes ❑ No
ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy and indicate the contraindication: _____

Section C: Ankylosing Spondylitis or Axial Spondyloarthritis

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 and no further questions.***
❑ Functional status ❑ Total spinal pain
❑ Inflammation (e.g., morning stiffness) ❑ None of the above

Initiation

21. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for active ankylosing spondylitis? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

22. 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 if not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section D: Crohn's Disease

23. 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

Continuation

24. 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

25. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for moderately to severely active Crohn's disease? ***ACTION REQUIRED: If 'Yes', attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.***
❑ Yes ❑ No

26. 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

27. 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 - Mercaptopurine (Purinethol)
- ❑ Yes - Metronidazole (Flagyl)
- ❑ Yes - Ciprofloxacin (Cipro)
- ❑ Yes - Prednisone
- ❑ Yes - Tacrolimus
- ❑ Yes - Budesonide (Entocort EC)
- ❑ Yes - Azathioprine (Azasan, Imuran)
- ❑ Yes -Methotrexate IM or SC
- ❑ Yes - Methylprednisolone (Solu-Medrol)
- ❑ Yes - Rifaximin (Xifaxan)
- ❑ No

28. 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 E: Psoriatic Arthritis

Continuation

29. 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. Please select all that apply***
    - ❑ Number of swollen joints
    - ❑ Number of tender joints
    - ❑ Dactylitis
    - ❑ Enthesitis
    - ❑ Skin and/or nail involvement
    - ❑ None of the above

Section F: Plaque Psoriasis

Continuation

30. 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 and no further questions.*** ❑ Yes ❑ No

31. 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

32. Has the patient ever received (including current utilizers) Otezla or a biologic (e.g., Humira) indicated for the treatment of moderate to severe plaque psoriasis? ***ACTION REQUIRED: If 'Yes', attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

33. 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 and no further questions.*** ❑ Yes ❑ No

34. 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.*

35. 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

36. 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: _____

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

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