Simponi Aria

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.

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*

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 the patient less than 21 years old or 65 years of age or older?
- ❑ Yes – less than 21 years old, *skip to Clinical Criteria Questions*
- ❑ Yes – age 65 years or older, *skip to Clinical Criteria Questions*
- ❑ No

C. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes, this is a continuation of an existing treatment
- ❑ No, this is a new therapy request (patient has not received requested medication in the last 6 months) *skip to Clinical Criteria Questions*

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

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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: 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: 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: Attach supporting clinical documentation.*** *Indicate and continue to Clinical Criteria Questions* ❑ Yes ❑ No

Criteria Questions:

1. What is the prescribed dose and frequency?
   a) Loading dose:
      ❑ Simponi Aria 50 mg Quantity and Frequency: _____
      ❑ Other _____
   b) Maintenance dose:
      ❑ Simponi Aria 50 mg 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 (PsA)
   ❑ Active ankylosing spondylitis (AS)
   ❑ Active articular juvenile idiopathic arthritis
   ❑ Polyarticular juvenile idiopathic arthritis
   ❑ Oligoarticular juvenile idiopathic arthritis
   ❑ Other _____

3. What is the ICD-10 code? _____

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

5. Will the requested drug be used in combination with any other biologic, (e.g., Humira) or targeted synthetic disease-modifying antirheumatic 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., Rinvoq, Olumiant, Xeljanz) associated with an increased risk of tuberculosis?
   If Yes, skip to #8 ❑ 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? *If Yes, skip to #10* ❑ Yes ❑ No

8. 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 #13*

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

10. What were the results of the TB test? ❑ Positive for TB ❑ Negative for TB, *skip to #13* ❑ Unknown

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

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

13. Is the patient currently receiving requested drug? ❑ Yes ❑ No

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

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

16. Has the patient achieved clinical remission 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

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

Section A: Rheumatoid Arthritis

Continuation

17. Has the patient achieved or maintained positive clinical response since starting treatment with the requested drug?
❑ Yes ❑ No

18. 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

19. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) that is indicated for moderately to severely active rheumatoid arthritis?
ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ❑ Yes ❑ No *If No, skip to #21*

20. Is Simponi Aria being prescribed in combination with methotrexate?
If Yes, no further questions ❑ Yes ❑ No ***If No, indicate clinical reason and no further questions:*** _____
_____

21. 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 #28.*** ❑ Yes ❑ No

22. 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 #28***
❑ Yes ❑ No

23. 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

24. 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

25. 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

26. 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

27. 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.

28. Is Simponi Aria being prescribed in combination with methotrexate? ❑ Yes ❑ No
If No, indicate clinical reason: _____

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

30. 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

31. 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 B: Psoriatic Arthritis

Continuation

32. 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.***
❑ Number of swollen joints ❑ Enthesitis
❑ Number of tender joints ❑ Skin and/or nail involvement
❑ Dactylitis ❑ None of the above

Section C: Ankylosing Spondylitis

Continuation

33. 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

34. 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.*** ❑ Yes ❑ No

35. 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: Articular Juvenile Idiopathic Arthritis

Continuation

36. 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.***
❑ 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

37. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic disease-modifying antirheumatic drug (DMARD) (e.g., Xeljanz) indicated for active articular juvenile idiopathic arthritis? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

38. Has the patient had an inadequate response to methotrexate or another non-biologic DMARD administered at an adequate dose and duration? ***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

39. Does the patient have any of the following risk factors?
❑ Positive rheumatoid factor ❑ Positive anti-cyclic citrullinated peptide antibodies
❑ Pre-existing joint damage ❑ None of the above

40. Does the patient meet any of the following?
❑ High-risk joints are involved (e.g., cervical spine, wrist, or hip) ❑ High disease activity
❑ High risk for disabling joint disease ❑ None of the above

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)**

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