Simponi, 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 1-866-249-6155**. 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:** _____
Request Initiated For: _____

1. What is the prescribed dose and frequency?
   a) Loading dose:
   - ❑ Simponi 50 mg Quantity and Frequency: _____
   - ❑ Simponi 100 mg Quantity and Frequency: _____
   - ❑ Simponi Aria 50 mg Quantity and Frequency: _____
   - ❑ Other _____

   b) Maintenance dose:
   - ❑ Simponi 50 mg Quantity and Frequency: _____
   - ❑ Simponi 100 mg Quantity and Frequency: _____
   - ❑ 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)
   - ❑ Moderately to severely active ulcerative colitis (UC)
   - ❑ Polyarticular juvenile idiopathic arthritis
   - ❑ Active ankylosing spondylitis (AS)
   - ❑ Active axial spondyloarthritis
   - ❑ Active articular juvenile idiopathic arthris
   - ❑ Oligoarticular juvenile idiopathic arthritis
   - ❑ Other _____

3. What is the ICD-10 code? _____

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

Section A: Preferred Product ***If Simponi Aria is being prescribed, skip to Section B: All Requests.***

5. These are the preferred products for which coverage is provided for treatment of the following indications when Simponi is being prescribed: *List continues on next page.*
   a) Ankylosing spondylitis: **Cosentyx, Enbrel, Humira, Remicade, Rinvoq, Simponi Aria, Cimzia syringe *(secondary)***
   b) Psoriatic arthritis: **Cosentyx, Enbrel, Humira, Otezla, Remicade, Rinvoq, Simponi Aria, Skyrizi (SC), Stelara (SC), and Tremfya, Cimzia syringe *(secondary)***

Send completed form to: Case Review Unit, CVS Caremark Prior Authorization Fax: 1-866-249-6155

c) Rheumatoid arthritis: **Enbrel, Humira, Kevzara, Orencia (SC)/Orencia ClickJect, Remicade, Rinvoq, Simponi Aria, Xeljanz/Xeljanz XR, Cimzia syringe** ***(secondary)***
d) Ulcerative colitis: **Humira, Remicade, Rinvoq, Stelara (IV), Stelara (SC), Xeljanz/Xeljanz XR, Zeposia**
Note: Secondary preferred product options only apply to members who have had a documented inadequate response or intolerable adverse event with primary preferred products.
Can the patient's treatment be switched to a preferred product?
❑ Yes - Please specify: _____ ***If Yes, please call 1-866-814-5506 to have the updated form faxed to your office OR you may complete the PA electronically (ePA). You may sign up online via CoverMyMeds at: www.covermymeds.com/epa/caremark/ or call 1-866-452-5017.***
❑ No ❑ Not applicable - Requested for condition not listed above, *skip to Section B: All Requests.*

6. Is this request for continuation of therapy with the requested product? ❑ Yes ❑ No *If No, skip to #8*

7. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? *If unknown, answer Yes.* ❑ Yes ❑ No *If No, skip to Section B: All Requests.*

8. Has the patient had a documented inadequate response or intolerable adverse event with any of the following preferred products? ***ACTION REQUIRED: If Yes, attach supporting chart note(s). Indicate ALL that apply.***

❑ Cimzia syringe:	❑ Inadequate response	❑ Intolerable adverse event
❑ Cosentyx:	❑ Inadequate response	❑ Intolerable adverse event
❑ Enbrel:	❑ Inadequate response	❑ Intolerable adverse event
❑ Humira:	❑ Inadequate response	❑ Intolerable adverse event
❑ Kevzara:	❑ Inadequate response	❑ Intolerable adverse event
❑ Orencia (SC)/Orencia ClickJect:	❑ Inadequate response	❑ Intolerable adverse event
❑ Otezla:	❑ Inadequate response	❑ Intolerable adverse event
❑ Rinvoq:	❑ Inadequate response	❑ Intolerable adverse event
❑ Skyrizi:	❑ Inadequate response	❑ Intolerable adverse event
❑ Stelara SC:	❑ Inadequate response	❑ Intolerable adverse event
❑ Tremfya:	❑ Inadequate response	❑ Intolerable adverse event
❑ Xeljanz/Xeljanz XR:	❑ Inadequate response	❑ Intolerable adverse event
❑ Zeposia:	❑ Inadequate response	❑ Intolerable adverse event

❑ None of the above

9. Does the patient have one of the following documented clinical reasons to avoid both of the preferred products that are JAK inhibitors (Rinvoq and Xeljanz/Xeljanz XR)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).***
❑ Yes - History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy - *Indicate drug(s):* _____
❑ Yes - History or risk of major adverse cardiovascular events (MI, stroke, etc.) - *Indicate drug(s):* _____
❑ Yes - History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.) - *Indicate drug(s):* _____
❑ Yes - History of hepatitis B or hepatitis C virus infection - *Indicate drug(s):* _____
❑ Yes - History of being a primary non-responder to a JAK inhibitor (i.e., no clinical response with initial treatment) - *Indicate drug(s):* _____
❑ No - None of the above

<u>Section B: All Requests</u>

10. Will the requested drug be used in combination with any other biologic, (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Otezla, Xeljanz)? ❑ Yes ❑ No

11. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Olumiant, Xeljanz) associated with an increased risk of tuberculosis?
If Yes, skip to #15 ❑ Yes ❑ No

12. 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

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

14. 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

15. Is the requested drug being prescribed by or in consultation with any of the following?
❑ Dermatologist ❑ Gastroenterologist ❑ Rheumatologist ❑ None of the above

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

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

18. 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 - Simponi ❑ Yes - Simponi Aria ❑ No ❑ Unknown

19. 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 C: Rheumatoid Arthritis

Continuation

20. Has the patient experienced substantial disease activity improvement (e.g., at least 20% from baseline) in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting positive clinical response and substantial disease activity improvement.***
❑ Yes ❑ No

Initiation

21. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (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 #23*

22. Is the requested drug being prescribed in combination with methotrexate or leflunomide? ❑ Yes ❑ No
If No, indicate a clinical reason for the patient to not use methotrexate or leflunomide:
_____

23. Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the RF 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 #25.***
❑ Yes ❑ No

24. 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

25. Is the requested drug being prescribed in combination with methotrexate or leflunomide? ❑ Yes ❑ No
If No, indicate a clinical reason for the patient to not use methotrexate or leflunomide:
_____

26. 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

27. 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

28. Is the requested drug being prescribed in combination with methotrexate? ❑ Yes ❑ No
If No, indicate a clinical reason for the patient to not use methotrexate:
_____

Section D: 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 and no further questions.***
❑ Number of swollen joints ❑ Enthesitis ❑ Number of tender joints
❑ Skin and/or nail involvement ❑ Dactylitis ❑ Axial disease
❑ None of the above

30. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) that is indicated for active psoriatic 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

31. Does the patient have mild to moderate disease? ❑ Yes ❑ No *If No, skip to #37*

32. Does the patient have enthesitis or predominantly axial disease? *If Yes, no further questions.* ❑ Yes ❑ No

33. Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) 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

34. Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? ***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

35. Is the requested drug being prescribed in combination with methotrexate or leflunomide?
ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy and no further questions. ❑ Yes ❑ No
If Yes, indicate the contraindication: _____

36. Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)?
ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.
❑ Yes ❑ No *No further questions.*

37. Does the patient have severe disease? ❑ Yes ❑ No

Section E: Ankylosing Spondylitis or Axial Spondyloarthritis
Continuation

38. 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

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

40. 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 (if applicable), including response to therapy. If therapy is if not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section F: Ulcerative Colitis - Simponi Only

41. 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

42. 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

43. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

44. Has the patient ever been hospitalized for acute severe 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 due to acute, severe ulcerative colitis and no further questions.***
    ❑ Yes ❑ No

45. 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 - Cyclosporine (Sandimmune)
    ❑ Yes - Mercaptopurine (Purinethol) ❑ Yes - Sulfasalazine
    ❑ Yes - Corticosteroid (e.g., hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone)
    ❑ Yes - Mesalamine (e.g., Asacol, Lialda, Pentasa, Canasa, Rowasa), balsalazide, or olsalazine
    ❑ Yes - Tacrolimus (Prograf) ❑ No

46. Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], corticosteroid [e.g., hydrocortisone, methylprednisolone, prednisone], cyclosporine [Sandimmune], mesalamine [Asacol, Lialda, Pentasa, Canasa, Rowasa], balsalazide, olsalazine, mercaptopurine [Purinethol], sulfasalazine, or tacrolimus [Prograf])? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy, or clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section G: Articular Juvenile Idiopathic Arthritis - Simponi Aria Only

Continuation

47. 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)
    ❑ Functional ability ❑ Number of joints with limitation of movement ❑ None of the above

Initiation

48. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz) that is 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

49. Has the patient had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) 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

50. Has the patient had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No *If No, skip to #76*

51. Does the patient have one of the following risk factors for poor outcome: a) involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ), b) presence of erosive disease or enthesitis, c) delay in diagnosis, d) elevated levels of inflammation markers, or e) symmetric disease? *If Yes, no further questions.* ❑ Yes ❑ No

52. Does the patient have any of the following risk factors for disease severity and potentially a more refractory disease course: a) positive rheumatoid factor, b) positive anti-cyclic citrullinated peptide antibodies, or c) pre-existing joint damage? ❑ Yes ❑ No

53. Does the patient meet any of the following: a) high-risk joints are involved (e.g., cervical spine, wrist, or hip), b) high disease activity, or c) high risk for disabling joint disease? ❑ 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 Prior Authorization Fax: 1-866-249-6155