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.

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Patient's Name: ______________________________ **Date**: _________________________________
Patient's ID: ________________________________ **Patient's Date of Birth:** ________________
Physician's Name: ____
Specialty: __________________________________ **NPI#:** _________________________________
Physician Office Telephone: __________________ **Physician Office Fax:** ___________________
Request Initiated For: ______________________

1. What drug is being prescribed? ❑ Simponi ❑ Simponi Aria ❑ Other _________________________

2. Has the patient been diagnosed with any of the following?
   ❑ Moderately to severely active rheumatoid arthritis (RA)
   ❑ Active psoriatic arthritis (PsA)
   ❑ Active axial spondyloarthritis
   ❑ Active ankylosing spondylitis (AS)
   ❑ Moderately to severely active ulcerative colitis (UC)
   ❑ Other _______________________________

3. What is the ICD-10 code? _______________

4. What is the patient's body weight? ____________ kg or lb ***(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:
   a) Ankylosing spondylitis: **Cosentyx, Enbrel, Humira**
   b) Psoriatic arthritis: **Cosentyx, Enbrel, Humira, Otezla**
   c) Rheumatoid arthritis: **Enbrel, Humira, Orencia (SC)/Orencia Clickject, Rinvoq, Xeljanz/Xeljanz XR**
   d) Ulcerative colitis: **Humira (primary), Stelara, Xeljanz/Xeljanz XR (secondary*)**
   Note: Secondary preferred products for UC are Stelara and Xeljanz/Xeljanz XR. The secondary preferred product option only applies to members who have had a documented inadequate response or intolerable adverse event with Humira.

   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.***

❑ 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
❑ Stelara:	❑ Inadequate response	❑ Intolerable adverse event
❑ Xeljanz/Xeljanz XR:	❑ Inadequate response	❑ Intolerable adverse event
❑ None of the above		

If None of the above, complete this form in its entirety and State Step Therapy section.

9. Does the patient have one of the following documented clinical reasons to avoid the preferred products that are TNF inhibitors (Enbrel and/or Humira)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).***
   ❑ Yes - History of demyelinating disorder - *Indicate drug(s):* ______________________________
   ❑ Yes - History of congestive heart failure- *Indicate drug(s):* ______________________________
   ❑ Yes - History of hepatitis B virus infection- *Indicate drug(s):* ____________________________
   ❑ Yes - Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
   Indicate drug(s): __________________________
   ❑ Yes - Risk of lymphoma- *Indicate drug(s):* ______________________________
   ❑ No - none of the above
   ❑ Not applicable - requested medication is not a TNF inhibitor
   If No - none of the above OR Not applicable – requested medication is a TNF inhibitor, complete this form in its entirety and State Step Therapy section.

Section B: All Requests

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

11. Has the patient ever received (including current utilizers) a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz)? *If Yes, skip to #13* ❑ Yes ❑ No

12. Has the patient had a TB test (e.g., a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray) within 6 months of initiating therapy? *If Yes, skip to #15* ❑ Yes ❑ No

13. Does the patient have risk factors for 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, or persons who work or reside with people who are at an increased risk for active TB)?
    ❑ Yes ❑ No *If No, skip to #18*

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

15. What were the results of the TB test? ❑ Positive for TB ❑ Negative for TB, *skip to #18* ❑ Unknown

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

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

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

19. Is this request for continuation of therapy? ❑ Yes ❑ No *If No, skip to diagnosis section.*

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

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

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

Section C: Rheumatoid Arthritis

22. Is the requested drug being prescribed in combination with methotrexate? ❑ Yes ❑ No
    If No, indicate clinical reason and no further questions: ____________________

23. Has the patient received a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) that is indicated for moderately to severely active rheumatoid arthritis? *If Yes, no further questions* ❑ Yes ❑ No

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

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

26. Does the patient have a contraindication to methotrexate? ❑ Yes ❑ No
    If Yes, indicate the contraindication: ____________________

Section D: Ankylosing Spondylitis or Axial Spondyloarthritis

27. Has the patient previously received a biologic indicated for active ankylosing spondylitis or axial spondyloarthritis? *If Yes, no further questions* ❑ Yes ❑ No

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

Section E: Ulcerative Colitis - Simponi Only

29. Has the patient previously received a biologic or targeted synthetic disease modifying drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis? *If Yes, no further questions* ❑ Yes ❑ No

30. Has the patient tried and had an inadequate response to at least one conventional therapy option?
    If Yes, indicate below and no further questions.
    ❑ Yes - Azathioprine (Azasan, Imuran)
    ❑ Yes - Corticosteroid (e.g., budesonide [Entocort, Uceris], hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone)
    ❑ Yes - Cyclosporine (Sandimmune)
    ❑ Yes - Mesalamine (e.g., Asacol, Lialda, Pentasa, Canasa, Rowasa)
    ❑ Yes - Mercaptopurine (Purinethol)
    ❑ Yes - Sulfasalazine
    ❑ Yes - Tacrolimus (Prograf)
    ❑ Yes - Metronidazole (Flagyl) or Ciprofloxacin (Cipro) (for pouchitis only)
    ❑ No

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

State Step Therapy

1. 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

2. 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

3. Does the patient reside in Maryland? ❑ Yes ❑ No *If No, skip to #7*

4. Is the alternate drug (see below) FDA-approved for the medical condition being treated? ❑ Yes ❑ No
   If No, please specify: ________________________________

5. Has the prescriber provided proof, documented in the patient's chart notes, indicating that the requested drug was ordered for the patient in the past 180 days? ❑ Yes ❑ No *If No, skip to #7*

6. 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 *No further questions*

7. Are any of the following conditions met for the alternate drug (see below)?
   ❑ The alternate drug is contraindicated
   ❑ The alternate drug is likely to cause an adverse reaction, physical or mental harm
   ❑ The alternate drug is expected to be ineffective
   ❑ The alternate drug was previously tried or a drug in the same class or with the same action was previously tried and was stopped due to ineffectiveness or an adverse event
   ❑ The alternate drug is not in the patient's best interest
   ❑ None of the above
   If Yes, please specify: ________________________________

8. Is the patient stable or currently receiving a positive therapeutic outcome with the requested drug and a change in the prescription drug is expected to be ineffective or cause harm to the patient? ❑ Yes ❑ No

Preferred drug(s) based on diagnosis:

a) Ankylosing spondylitis (AS): **Cosentyx, Enbrel, Humira**
b) Psoriatic arthritis (PsA): **Cosentyx, Enbrel, Humira, Otezla**
c) Rheumatoid arthritis: **Enbrel, Humira, Kevzara, Orencia (SC)/Orencia Clickject, Rinvoq, Xeljanz/Xeljanz XR**
d) Ulcerative colitis: **Humira (primary), Stelara, Xeljanz/Xeljanz XR (secondary)**

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

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