Actemra

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?
   - ❑ Actemra IV 80 mg Quantity and Frequency: _____
   - ❑ Actemra SQ 162 mg syringe Quantity and Frequency: _____
   - ❑ Actemra SQ 162 mg Actpen autoinjector Quantity and Frequency:_____
   - ❑ Actemra IV 200 mg Quantity and Frequency: _____
   - ❑ Actemra IV 400 mg Quantity and Frequency: _____
   - ❑ Other _____

2. What is the diagnosis?
   - ❑ Moderately to severely active rheumatoid arthritis (RA)
   - ❑ Active systemic juvenile idiopathic arthritis (sJIA)
   - ❑ Active articular juvenile idiopathic arthritis
   - ❑ Polyarticular juvenile idiopathic arthritis (pJIA)
   - ❑ Oligoarticular juvenile idiopathic arthritis
   - ❑ Multicentric Castleman disease
   - ❑ Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
   - ❑ Giant cell arteritis
   - ❑ Immunotherapy-related inflammatory arthritis
   - ❑ Unicentric Castleman disease
   - ❑ Cytokine release syndrome
   - ❑ Acute graft versus host disease
   - ❑ Other _____

3. What is the ICD-10 code? _____

4. What is the patient's weight? _____ kg

Section A: Preferred Product

5. These are the preferred products for which coverage is provided for the treatment of rheumatoid arthritis: **Enbrel, Humira, Kevzara, Orencia (SC)/Orencia Clickject, Remicade, Rinvoq, Simponi Aria, Xeljanz/Xeljanz XR, Cimzia syringe (secondary)*. *This preferred product option only applies to members who have had a documented inadequate response or intolerable adverse event with two 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 - Continue request for non-preferred product, Actemra
   - ❑ Not applicable - Diagnosis is not rheumatoid arthritis, *skip to Section B: All Requests.*

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

6. Is the 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. Does the patient have 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
❑ Enbrel:	❑ Inadequate response	❑ Intolerable adverse event
❑ Humira:	❑ Inadequate response	❑ Intolerable adverse event
❑ Kevzara:	❑ Inadequate response	❑ Intolerable adverse event
❑ Orencia (SC/ClickJect):	❑ Inadequate response	❑ Intolerable adverse event
❑ Rinvoq:	❑ Inadequate response	❑ Intolerable adverse event
❑ Xeljanz/Xeljanz XR:	❑ Inadequate response	❑ Intolerable adverse event
❑ Remicade:	❑ Inadequate response	❑ Intolerable adverse event
❑ Simponi Aria:	❑ Inadequate response	❑ Intolerable adverse event

❑ No - None of the above

9. Does the patient have any of the following?
   ❑ Documented clinical reason(s) to avoid TNF inhibitors
   ❑ Documented clinical reason(s) to avoid JAK inhibitors, *skip to #11*
   ❑ Documented clinical reason(s) to avoid TNF inhibitors and JAK inhibitors
   ❑ None of the above

10. Does the patient have one of the following documented clinical reasons to avoid all of the preferred products that are TNF inhibitors (Remicade, Simponi Aria, Cimzia syringe, Enbrel, and Humira)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).***
    ❑ Yes – History of demyelinating disorder
    ❑ Yes – History of congestive heart failure
    ❑ Yes – History of hepatitis B virus infection
    ❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
    ❑ Yes – History or risk of lymphoma or other malignancy
    ❑ Yes – History of being a primary non-responder to a TNF inhibitor (i.e., no clinical response with initial treatment)
    ❑ No - None of the above

11. 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
    ❑ Yes – History or risk of major adverse cardiovascular events (MI, stroke, etc.)
    ❑ Yes – History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.)
    ❑ Yes – History of hepatitis B or hepatitis C virus infection
    ❑ Yes – History of being a primary non-responder to a JAK inhibitor (i.e., no clinical response with initial treatment)
    ❑ No - None of the above

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

12. 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

13. Is the requested drug being prescribed by or in consultation with any of the following specialists?
    ❑ Rheumatologist ❑ Oncologist ❑ Hematologist ❑ Pulmonologist ❑ None of the above

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

15. 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

16. What were the results of the tuberculosis (TB) test?
❑ Positive for TB ❑ Negative for TB, *skip to Section C.* ❑ Unknown

17. 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

Section C: All Requests (Excludes Immunotherapy-Related Inflammatory Arthritis and Cytokine Release Syndrome)

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

19. 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 ❑ No ❑ Unknown

20. *If diagnosis is articular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis or giant cell arteritis,* has the patient achieved or maintained a 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

21. *If diagnosis is unicentric or multicentric castleman disease,* is there evidence of unacceptable toxicity or disease progression on the current regimen? ❑ Yes ❑ No

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

Section D: Rheumatoid Arthritis

Continuation

22. Has the patient achieved or maintained a positive clinical response since starting treatment with the requested drug?
❑ Yes ❑ No *If No, skip to #24*

23. 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 and skip to #25.*** ❑ Yes ❑ No

24. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency? ❑ Yes ❑ No

25. Please select the situation that applies to the patient. *Indicate ALL that apply.*
a) Patient is continuing therapy on current: ❑ Dose AND frequency ❑ Dose only ❑ Frequency only
b) Prescriber is increasing: ❑ Dose AND frequency ❑ Dose only ❑ Frequency only
c) Prescriber is decreasing: ❑ Dose AND frequency ❑ Dose only ❑ Frequency only

26. *If request is for intravenous administration,* does the patient require an increased dose due to lack of clinical response at the current dose? ❑ Yes ❑ No ❑ N/A - An increased dose is not requested

27. *If request is for subcutaneous administration,* does the patient require an increased dosing frequency due to lack of clinical response at the current dose? ❑ Yes ❑ No ❑ N/A - An increased dosing frequency is not requested

Initial

28. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

29. 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 #31.***
❑ Yes ❑ No

30. 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

31. 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

32. 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

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

34. Please indicate the contraindication to methotrexate.
❑ Drug interaction
❑ Breastfeeding
❑ Hypersensitivity
❑ Risk of treatment-related toxicity
❑ Pregnancy or currently planning pregnancy
❑ History of intolerance or adverse event
❑ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
❑ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
❑ Other _____

Section E: Polyarticular and Oligoarticular 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

Initial

36. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz) indicated for the treatment of active articular juvenile idiopathic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

37. 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

38. 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 #40*

39. 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

40. 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

41. 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

Section F: Systemic Juvenile Idiopathic Arthritis (sJIA)

Continuation

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.***
❑ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
❑ Functional ability
❑ Number of joints with limitation of movement
❑ Systemic features (e.g., fevers, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)
❑ None of the above

Initial

43. Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for the treatment of active systemic juvenile idiopathic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***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. Does the patient have active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)? ❑ Yes ❑ No

45. Has the patient had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or systemic glucocorticoids? ***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 G: Unicentric Castleman Disease

46. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

Initial

47. Has the patient been tested for human immunodeficiency virus (HIV)? ❑ Yes ❑ No

48. What were the results of the HIV test? ❑ Positive ❑ Negative ❑ Unknown

49. Has the patient been tested for herpesvirus-8? ❑ Yes ❑ No

50. What were the results of the herpesvirus-8 test? ❑ Positive ❑ Negative ❑ Unknown

51. Has the disease progressed following treatment of relapsed or refractory disease? ❑ Yes ❑ No

52. Will the requested drug be used as a single agent? ❑ Yes ❑ No

Section H: Multicentric Castleman Disease

53. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

Initial

54. Has the disease progressed following treatment of relapsed/refractory or progressive disease? ❑ Yes ❑ No

55. Will the requested drug be used as a single agent? ❑ Yes ❑ No

Section I: Immunotherapy-Related Inflammatory Arthritis

56. Is the disease severe or refractory? ❑ Yes ❑ No

57. Has the patient experienced an inadequate response to systemic corticosteroids? ***ACTION REQUIRED: If Yes, please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #59.*** ❑ Yes ❑ No

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

59. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

Section J: Giant Cell Arteritis

Continuation

60. 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.***
    - ❑ Headaches
    - ❑ Scalp tenderness
    - ❑ Jaw and/or tongue claudication
    - ❑ Limb claudication
    - ❑ Tenderness and/or thickening of superficial temporal arteries
    - ❑ Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
    - ❑ Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
    - ❑ Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
    - ❑ None of the above

Initial

61. Has the diagnosis been confirmed by temporal artery biopsy or cross-sectional imaging? *If Yes, no further questions.* ❑ Yes ❑ No

62. Has the diagnosis been confirmed by acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP])? ❑ Yes ❑ No

Section K: Cytokine Release Syndrome

63. Has the patient been diagnosed with chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS)? *If Yes, no further questions.* ❑ Yes ❑ No

64. Does the patient have refractory cytokine release syndrome (CRS) related to blinatumomab therapy? ***ACTION REQUIRED: If Yes, please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

Section L: Acute Graft Versus Host Disease

65. Has the patient experienced an inadequate response to systemic corticosteroids? ***ACTION REQUIRED: If Yes, please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #67.*** ❑ Yes ❑ No

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

67. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

Section M: Systemic Sclerosis-Associated Interstitial Lung Disease

68. Has the diagnosis been confirmed by a high-resolution computed tomography (HRCT) study of the chest?
ACTION REQUIRED: If Yes, please attach the radiology report. ❑ 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