Kineret

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 is the prescribed dose and frequency?
   ❑ Kineret 100mg Quantity and Frequency: _____
   ❑ Other: _____

2. *If the diagnosis is adult-onset Still's disease (AOSD), active systemic juvenile idiopathic arthritis (sJIA), recurrent pericarditis, multicentric Castleman's disease, hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), Schnitzler's syndrome, gout flares, pseudogout, CAR T-cell related toxicities, or Erdheim-Chester disease*, 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 ❑ N/A - diagnosis is not listed above

3. What is the diagnosis?
   ❑ Moderately to severely active rheumatoid arthritis (RA)
   ❑ Adult-onset Still's disease (AOSD)
   ❑ Active systemic juvenile idiopathic arthritis (sJIA)
   ❑ Recurrent pericarditis
   ❑ Multicentric Castleman disease
   ❑ Schnitzler syndrome
   ❑ Polyarticular juvenile idiopathic arthritis
   ❑ Gout flares
   ❑ Deficiency of interleukin-1 receptor antagonist (DIRA)
   ❑ Erdheim-Chester disease
   ❑ Cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID) (also known as chronic infantile neurologic cutaneous and articular syndrome [CINCA])
   ❑ Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD)
   ❑ Pseudogout (also known as calcium pyrophosphate deposition disease)
   ❑ Chimeric antigen receptor (CAR) T-cell related toxicities - Cytokine release syndrome (CRS)
   ❑ Other _____

4. What is the ICD-10 code? _____

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

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Section A: Preferred Product

6. These are the preferred products for which coverage is provided for the treatment of the following indication: Rheumatoid arthritis: **Enbrel, Humira, Kevzara, Orencia (SC)/Orencia ClickJect, Remicade, Rinvoq, Simponi Aria, Xeljanz/Xeljanz XR, Cimzia syringe (secondary)*.** Can the patient's treatment be switched to a preferred product? ***Note: Secondary preferred product option only applies to members who have had a documented inadequate response or intolerable adverse event with two primary preferred products.***

   ❑ 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*

7. Is the request for continuation of therapy with the requested product? ❑ Yes ❑ No *If No, skip to #9*

8. 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.*

9. Does the patient have a documented inadequate response or intolerable adverse event with any of the following primary preferred products indicated for rheumatoid arthritis (Enbrel, Humira, Kevzara, Orencia SC/Orencia ClickJect, Rinvoq, and Xeljanz/Xeljanz XR) and the secondary preferred product (Cimzia syringe)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).*** *Indicate ALL that apply.*

❑ 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
❑ Rinvoq:	❑ Inadequate response	❑ Intolerable adverse event
❑ Xeljanz/Xeljanz XR:	❑ Inadequate response	❑ Intolerable adverse event
❑ Cimzia syringe	❑ Inadequate response	❑ Intolerable adverse event

   ❑ No - None of the above

10. 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 #12*
    ❑ Documented clinical reason(s) to avoid TNF inhibitors and JAK inhibitors
    ❑ None of the above

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

12. 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).*** *Question continues on next page.*
    ❑ Yes – History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, *please specify product(s):* _____
    ❑ Yes – History or risk of major adverse cardiovascular events (MI, stroke, etc.), *please specify product(s):* _____
    ❑ Yes – History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.),

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please specify product(s): _____
❑ Yes – History of hepatitis B or hepatitis C virus infection, *please specify product(s):* _____
❑ Yes – History of being a primary non-responder to a JAK inhibitor (i.e., no clinical response with initial treatment), *please specify product(s):* _____
❑ No - None of the above

Section B: All Requests

13. 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

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?
If Yes, skip to #18 ❑ 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 #18* ❑ 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

18. Is the requested drug being prescribed by or in consultation with a:
❑ Cardiologist ❑ Dermatologist ❑ Hematologist ❑ Immunologist ❑ Oncologist ❑ Rheumatologist

19. Is this request for continuation of therapy with the requested drug?
❑ 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, or diagnosis is Rheumatoid arthritis, skip to diagnosis section.*
❑ Yes ❑ No ❑ Unknown

21. *If diagnosis is Multicentric Castleman's disease,* has the patient experienced disease progression or an unacceptable toxicity? *If Yes or No, no further questions.* ❑ Yes ❑ No ❑ N/A, diagnosis not listed

22. Has the patient achieved or maintained a positive clinical response to treatment 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

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

24. 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: Please attach chart notes or medical record documentation supporting positive clinical response.*** ❑ Yes ❑ No

Initiation

25. 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

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26. 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 #28.***
❑ Yes ❑ No

27. 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

28. 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 skip to #32.*** ❑ Yes ❑ No

29. Has the patient experienced 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 skip to #32.*** ❑ Yes ❑ No

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

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

32. Has the patient experienced an inadequate response after at least 3 months of treatment OR an intolerance to a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz)? ***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 D: Adult-Onset Still's Disease

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 a 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
❑ Systemic features (e.g., fevers, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)
❑ None of the above

Initiation

34. 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 active adult-onset Still's disease (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

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35. Does the patient have active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or sore throat)? ❑ Yes ❑ No

36. Has the patient experienced an inadequate response to a trial of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or a conventional synthetic drug (e.g., methotrexate)? ❑ Yes ❑ No

Section E: Systemic Juvenile Idiopathic Arthritis

Continuation

37. 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.***
List continues on next page.
❑ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
❑ Number of joints with limitation of movement
❑ Functional ability
❑ Systemic features (e.g., fevers, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) ❑ None of the above

Initiation

38. 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 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

39. Does the patient have active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)? ❑ Yes ❑ No

40. 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 F: Cryopyrin-Associated Periodic Syndromes (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Continuation

41. 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.***
❑ Fever
❑ Skin rash
❑ Joint pain and/or inflammation
❑ Central nervous system (CNS) symptoms (e.g., meningitis, headache, cerebral atrophy, uveitis, hearing loss)
❑ Inflammatory markers (e.g., serum amyloid A [SAA], C-reactive protein [CRP], erythrocyte sedimentation rate [ESR])
❑ None of the above

Section G: Recurrent Pericarditis

Continuation

42. Has the patient experienced a decreased recurrence of pericarditis? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting a positive clinical response and no further questions.*** ❑ Yes ❑ No

43. Has the patient experienced an improvement in signs and symptoms of the condition? ❑ Yes ❑ No

44. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting a positive clinical response.***
❑ Pericarditic chest pain
❑ Pericardial rubs
❑ Electrocardiogram (ECG)
❑ Pericardial effusion
❑ C-reactive protein (CRP)
❑ None of the above

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Initiation

45. Has the patient had at least two episodes of pericarditis? ❑ Yes ❑ No

46. Has the patient failed at least 2 agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids)? ***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 H: Multicentric Castleman Disease

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

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

Section I: Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

49. Has the patient had active flares within the last 6 months? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation indicating number of active flares within the last 6 months.*** ❑ Yes ❑ No

50. What is the patient's Physician's Global Assessment (PGA) score? ***ACTION REQUIRED: Please attach chart notes or medical record documentation indicating Physician's Global Assessment score.*** _____ ❑ Unknown *If greater than or equal to 2, no further questions.*

51. What is the patient's C-reactive protein (CRP) level in mg/L? ***ACTION REQUIRED: Please attach laboratory result indicating patient's C-reactive protein (CRP) level.*** _____ mg/L ❑ Unknown

Section J: Schnitzler Syndrome

52. Does the patient have an urticarial rash and monoclonal IgM (or IgG) gammopathy? ❑ Yes ❑ No

53. Does the patient have at least 2 of the following signs and symptoms? ❑ Yes ❑ No
    a. Fever
    b. Joint pain or inflammation
    c. Bone pain
    d. Lymphadenopathy
    e. Hepatomegaly or splenomegaly
    f. Leukocytosis
    g. Elevated erythrocyte sedimentation rate (ESR)
    h. Abnormalities on bone morphological study (e.g., increased bone density)

54. Have other possible causes of the signs and symptoms been ruled out, including but not limited to: hyperimmunoglobulin D syndrome, adult-onset Still's disease, urticarial hypocomplementemic vasculitis, acquired C1 inhibitor deficiency and cryoglobulinemia? ❑ Yes ❑ No

Section K: Gout/Pseudogout Flares

55. Has the patient had an inadequate response or intolerance to maximum tolerated doses of non-steroidal anti inflammatory drugs (NSAIDs) or has a contraindication to 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 not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

56. Has the patient had an inadequate response or intolerance to maximum tolerated doses of colchicine or has a contraindication to colchicine? ***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 not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

57. Has the patient had an inadequate response or intolerance to maximum tolerated doses of oral and injectable corticosteroids? ***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

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58. Does the patient have a clinical reason to avoid repeated courses of corticosteroids? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section L: Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

59. Has the diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) been genetically confirmed? ❑ Yes ❑ No

60. Does the patient have *IL1RN* mutations? ***ACTION REQUIRED: If Yes, please attach documentation of IL1RN mutation status.*** ❑ Yes ❑ No

Section M: Chimeric Antigen Receptor (CAR) T-Cell Related Toxicities

61. Does the patient have CAR T-cell induced cytokine release syndrome that is refractory to high dose corticosteroids and anti-IL-6 (anti-interleukin-6) therapy (e.g., Actemra)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

62. Will the requested drug be used as a replacement for the second dose of tocilizumab when supplies are limited or unavailable? ❑ 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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