CVS caremark™ {{PANUMCODE}}

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: {{MEMFIRST}} {{MEMLAST}} **Date**: {{TODAY}}
Patient's ID: {{MEMBERID}} **Patient's Date of Birth:** {{MEMBERDOB}}
Physician's Name: {{PHYFIRST}} {{PHYLAST}}
Specialty: _____, **NPI#:** _____
Physician Office Telephone: {{PHYSICIANPHONE}} **Physician Office Fax:** {{PHYSICIANFAX}}
Request Initiated For: {{DRUGNAME}}

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, or gout flares*, 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)
   ❑ Cryopyrin-Associated Periodic Syndrome (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID), (also known as chronic infantile neurologic cutaneous and articular syndrome [CINCA])
   ❑ Recurrent pericarditis
   ❑ Multicentric Castleman's disease
   ❑ Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
   ❑ Schnitzler's syndrome
   ❑ Gout flares
   ❑ Management of flares for gout or pseudogout (also known as calcium pyrophosphate deposition disease)
   ❑ Polyarticular juvenile idiopathic arthritis
   ❑ Deficiency of interleukin-1 receptor antagonist (DIRA)
   ❑ Other _____

4. What is the ICD-10 code? _____

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

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

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.** 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*

7. Is this 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 preferred products indicated for rheumatoid arthritis? ***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/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 one of the following documented clinical reasons to avoid the preferred products that are TNF inhibitors (Enbrel, Humira, Cimzia syringe)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).***
    ❑ Yes - History of demyelinating disorder
    ❑ Yes - History of congestive heart failure
    ❑ Yes - Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
    ❑ Yes - History of hepatitis B virus infection
    ❑ Yes - Risk of lymphoma
    ❑ No - none of the above
    ❑ Not applicable - requested medication is a TNF inhibitor

Section B: All Requests

11. Will the requested drug be used in combination with any other biologic or targeted synthetic disease-modifying anti-rheumatic drug (DMARD)? ❑ Yes ❑ No

12. Has the patient ever received (including current utilizers) a biologic or targeted synthetic DMARD? *If Yes, skip to #14* ❑ Yes ❑ No

13. 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 #16* ❑ Yes ❑ No

14. 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 #19*

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

16. What were the results of the tuberculosis (TB) test?
    ❑ Positive for TB ❑ Negative for TB, *skip to #19* ❑ Unknown

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

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

19. Is this request for continuation of therapy with Kineret? ❑ 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? ❑ Yes ❑ No *No further questions*

22. 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

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. 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.***

Initiation

25. Has the patient ever received (including current utilizers) a biologic or targeted synthetic disease modifying antirheumatic 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 and no further questions.*** ❑ Yes ❑ No

26. 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 #33.*** ❑ Yes ❑ No

27. 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 #33.***
❑ Yes ❑ No

28. 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

29. 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

30. 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

31. 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

32. 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

33. 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 #36.*** ❑ Yes ❑ No

34. 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 #46.*** ❑ Yes ❑ No

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

36. Has the patient experienced an inadequate response after at least 3 months of treatment OR intolerance to a biologic or targeted synthetic DMARD (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

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.
❑ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
❑ Number of joints with limitation of movement
❑ Functional ability
❑ Systemic symptoms (e.g., fevers, evanescent skin rashes)
❑ None of the above

Initiation

38. Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate or corticosteroids? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried.*** ❑ Yes ❑ No *If No, skip to #40*

39. Will the patient receive Kineret concurrently with methotrexate or corticosteroids?
If Yes, no further questions ❑ Yes ❑ No

40. Does the patient have intolerance or a contraindication to low-dose corticosteroids?
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 not advisable, please attach documentation of clinical reason to avoid therapy. ❑ Yes ❑ No

41. Does the patient have intolerance or a contraindication to methotrexate? ***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 not advisable, please attach documentation of clinical reason to avoid therapy.***
❑ Yes - Intolerance, *no further questions*
❑ Yes - Contraindication, *indicate the contraindication:* _____
❑ No

Section E: Systemic Juvenile Idiopathic Arthritis

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)
❑ Number of joints with limitation of movement ❑ Functional ability
❑ Systemic symptoms (e.g., fevers, evanescent skin rashes) ❑ None of the above

Initiation

43. Has the patient ever received (including current utilizers) a biologic indicated for active systemic 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

44. Has the patient experienced an inadequate response to any of the following medications after treatment for the specified duration? ***ACTION REQUIRED: If Yes, please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.***
    ❑ Yes - At least a 1-month trial of nonsteroidal anti-inflammatory drugs (NSAIDs)
    ❑ Yes - At least a 2-week trial of corticosteroids
    ❑ Yes - At least a 3-month trial of methotrexate or leflunomide
    ❑ No

Section F: Cryopyrin-Associated Periodic Syndrome (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Continuation

45. 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

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

Initiation

47. Has the patient failed a first-line therapy agent for the treatment of recurrent pericarditis (i.e., colchicine)? ***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's Disease

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

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

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

50. 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

51. What is the patient's Physician's Global Assessment 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.

52. 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's Syndrome

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

54. Does the patient have at least 2 of the following signs and symptoms? *If Yes, indicate all that apply.*
    - ❑ Fever
    - ❑ Joint pain or inflammation
    - ❑ Bone Pain
    - ❑ Palpable lymph nodes
    - ❑ Elevated red blood cell (erythrocyte) sedimentation rate
    - ❑ Elevated numbers of white blood cells (leukocytosis)
    - ❑ Enlargement of the liver or spleen
    - ❑ Abnormalities on bone morphological study (e.g., increased bone density)
    - ❑ No

55. 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

56. 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, 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 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, including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

58. Has the patient had an inadequate response or intolerance to maximum tolerated doses of oral and injectable corticosteroid? ***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 not advisable, please attach documentation of clinical reason to avoid therapy and no further questions.*** ❑ Yes ❑ No

59. 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)

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

61. Does the patient have DIRA due to *IL1RN* mutations? ***ACTION REQUIRED: If Yes, please attach documentation of IL1RN mutation status.*** ❑ 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