Kineret

HMSACOM - 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 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** 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:** __________________
Patient's Phone Number: _________________________________
Physician's Name: ____
Specialty: ___________________________________ **NPI#:** __________________________________
Physician Office Telephone: ___________________ **Physician Office Fax:** ____________________

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: __________________________*kg*

Patient Height: ____________*ft* ___________*inches*

Indicate where the drug is being dispensed:

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

Indicate where the drug is being administered:

❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
❑ Office ❑ Outpatient Hospital ❑ Pharmacy

What is the ICD-10 code? _______________

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Exception Criteria Questions:

A. Is the product being requested for the treatment of an ADULT patient (18 years of age or older) with one of the following indications?

- Ankylosing spondylitis
- Crohn's disease
- Plaque psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis

❒ Yes, *Continue to Question B*
❒ No, *skip to Criteria Questions*

B. These are the preferred products for which coverage is provided for the treatment of the following indications:

- Ankylosing spondylitis: adalimumab-adaz, Avsola, Cosentyx IV/SQ, Enbrel, Hadlima, Hyrimoz (Cordavis brand), Inflectra, Rinvoq, Simponi Aria, and Taltz
- Crohn's disease: adalimumab-adaz, Avsola, Entyvio, Hadlima, Hyrimoz (Cordavis brand), Inflectra, Pyzchiva IV/SQ (Cordavis or Sandoz brand), Rinvoq, Skyrizi IV/SQ, Tremfya IV/SQ, and Yesintek IV/SQ
- Plaque psoriasis: adalimumab-adaz, Avsola, Cosentyx SQ, Enbrel, Hadlima, Hyrimoz (Cordavis brand), Inflectra, Otezla, Pyzchiva SQ (Cordavis or Sandoz brand), Skyrizi SQ, Taltz, Tremfya SQ, and Yesintek SQ
- Psoriatic arthritis: adalimumab-adaz, Avsola, Cosentyx IV/SQ, Enbrel, Hadlima, Hyrimoz (Cordavis brand), Inflectra, Otezla, Pyzchiva SQ (Cordavis or Sandoz brand), Rinvoq, Simponi Aria, Skyrizi SQ, Taltz, Tremfya SQ, Xeljanz/Xeljanz XR, and Yesintek SQ
- Rheumatoid arthritis: adalimumab-adaz, Avsola, Enbrel, Hadlima, Hyrimoz (Cordavis brand), Inflectra, Rinvoq, Simponi Aria, and Xeljanz/Xeljanz XR
- Ulcerative colitis: adalimumab-adaz, Avsola, Entyvio, Hadlima, Hyrimoz (Cordavis brand), Inflectra, Pyzchiva IV/SQ (Cordavis or Sandoz brand), Rinvoq, Skyrizi IV/SQ, Tremfya IV/SQ, Velsipity, Xeljanz/Xeljanz XR, and Yesintek IV/SQ

Can the patient's treatment be switched to a preferred product?
❒ Yes, *Please obtain Form for preferred product and submit for corresponding PA*.
❒ No, *Continue to Question C*

C. Is this request for continuation of therapy with the requested product?
❒ Yes, *Continue to Question D*
❒ No, *Continue to Question E*

D. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer 'Yes'
❒ Yes, *Continue to Question E*
❒ No, *skip to Criteria Questions*

E. What is the diagnosis?
❒ Ankylosing spondylitis, *Continue to Question F*
❒ Crohn's disease, *Continue to Question I*
❒ Plaque psoriasis, *Continue to Question L*
❒ Psoriatic arthritis, *Continue to Question O*
❒ Rheumatoid arthritis, *Continue to Question R*
❒ Ulcerative colitis, *Continue to Question S*

F. Is the requested product self-administered (oral or self-injected)?
❒ Yes, *Continue to Question G*
❒ No, *Continue to Question H*

G. Does the patient have a documented inadequate response, intolerable adverse event or contraindication to all of the following preferred products indicated for ankylosing spondylitis: Cosentyx SQ, Enbrel, Rinvoq, Taltz, and adalimumab-adaz, Hyrimoz (Cordavis brand) or Hadlima? ***ACTION REQUIRED**: Please submit supporting documentation*
❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

H. Does the patient have a documented inadequate response, intolerable adverse event or contraindication to all of the following preferred products indicated for ankylosing spondylitis: Cosentyx IV, Avsola or Inflectra IV, and Simponi Aria? ***ACTION REQUIRED**: Please submit supporting documentation*
❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

I. Is the requested product self-administered (oral or self-injected)?
❒ Yes, *Continue to Question J*
❒ No, *Continue to Question K*

J. Does the patient have a documented inadequate response, intolerable adverse event or contraindication to ALL of the following preferred products indicated for Crohn's disease? ***ACTION REQUIRED**: Please submit supporting documentation*

- Rinvoq, Skyrizi SQ AND Tremfya SQ
- adalimumab-adaz, Hyrimoz (Cordavis brand) OR Hadlima
- Pyzchiva SQ (Cordavis or Sandoz brand) OR Yesintek SQ

❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

K. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to ALL of the following preferred products indicated for Crohn's disease? ***ACTION REQUIRED**: Please submit supporting documentation*

- Entyvio, Skyrizi IV, AND Tremfya IV
- Pyzchiva IV (Cordavis or Sandoz brand) OR Yesintek IV
- Avsola OR Inflectra

❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

L. Is the requested product self-administered (oral or self-injected)?
❒ Yes, *Continue to Question M*
❒ No, *Continue to Question N*

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CVS Caremark Specialty Programs ● 2969 Mapunapuna Place ● Honolulu, HI 96819
Phone: 1-808-254-4414 ● Fax: 1-866-237-5512 ● www.caremark.com

M. Does the patient have a documented inadequate response, intolerable adverse event or contraindication to ALL of the following preferred products indicated for plaque psoriasis? ***ACTION REQUIRED****: Please submit supporting documentation*

- Cosentyx SQ, Enbrel, Otezla, Skyrizi SQ, Taltz AND Tremfya SQ
- adalimumab-adaz, Hyrimoz (Cordavis brand) OR Hadlima
- Pyzchiva SQ (Cordavis or Sandoz brand) OR Yesintek SQ

❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

N. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to the following preferred products indicated for plaque psoriasis: Avsola OR Inflectra? ***ACTION REQUIRED****: Please submit supporting documentation*
❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

O. Is the requested product self-administered (oral or self-injected)?
❒ Yes, *Continue to Question P*
❒ No, *Continue to Question Q*

P. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to ALL of the following preferred products indicated for psoriatic arthritis? ***ACTION REQUIRED****: Please submit supporting documentation*

- Cosentyx SQ, Enbrel, Otezla, Rinvoq, Skyrizi SQ, Taltz, Tremfya SQ AND Xeljanz/Xeljanz XR
- adalimumab-adaz, Hyrimoz (Cordavis brand) OR Hadlima?
- Pyzchiva SQ (Cordavis or Sandoz brand) OR Yesintek SQ

❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

Q. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to all of the following preferred products indicated for psoriatic arthritis: Cosentyx IV, Avsola OR Inflectra and Simponi Aria? ***ACTION REQUIRED****: Please submit supporting documentation*
❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

R. Does the patient have a documented inadequate response, intolerable adverse event or contraindication to all of the following preferred products indicated for rheumatoid arthritis: Enbrel, Rinvoq, Xeljanz/Xeljanz XR, and adalimumab-adaz, Hyrimoz (Cordavis brand) or Hadlima? ***ACTION REQUIRED****: Please submit supporting documentation*
❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

S. Is the requested product self-administered (oral or self-injected)?
❒ Yes, *Continue to Question T*
❒ No, *Continue to Question U*

T. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to ALL of the following preferred products indicated for ulcerative colitis? ***ACTION REQUIRED****: Please submit supporting documentation*

- Rinvoq, Skyrizi SQ, Tremfya SQ, Velsipity, AND Xeljanz/Xeljanz XR
- adalimumab-adaz, Hyrimoz (Cordavis brand) OR Hadlima
- Pyzchiva SQ (Cordavis or Sandoz brand) OR Yesintek SQ

❒ Yes, *skip to Criteria Questions*
❒ No, *skip to Criteria Questions*

U. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to ALL of the following preferred products indicated for ulcerative colitis? ***ACTION REQUIRED****: Please submit supporting documentation*

- Entyvio, Skyrizi IV, AND Tremfya IV
- Pyzchiva IV (Cordavis or Sandoz brand) OR Yesintek IV
- Avsola OR Inflectra

❒ Yes, *Continue to Criteria Questions*
❒ No, *Continue to Criteria Questions*

Criteria Questions:
General Biologic/Targeted Synthetic Drug and TB

1. 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, *Continue to #2*
❐ No, *Continue to #2*

2. 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?
❐ Yes, *Continue to #9*
❐ No, *Continue to #3*

3. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 6 months of initiating therapy?
❐ Yes, *Continue to #4*
❐ No, *Continue to #4*

4. What were the results of the tuberculosis (TB) test?
❐ Positive for TB, *Continue to #5*
❐ Negative for TB, *Continue to #9*
❐ Unknown, *No Further Questions*

5. Which of the following applies to the patient?
❐ Patient has latent TB and treatment for latent TB has been initiated, *Continue to #9*
❐ Patient has latent TB and treatment for latent TB has been completed, *Continue to #9*
❐ Patient has latent TB and treatment for latent TB has not been initiated, *Continue to #9*
❐ Patient has active TB, *Continue to #9*

Indication

9. What is the diagnosis?
❐ Rheumatoid arthritis (RA), *Continue to #100*
❐ Adult-onset Still's disease (AOSD), *Continue to #150*
❐ Systemic juvenile idiopathic arthritis (sJIA), *Continue to #200*
❐ Cryopyrin-associated periodic syndrome (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID) (also known as chronic infantile neurologic cutaneous and articular syndrome [CINCA]), *Continue to #250*
❐ Recurrent pericarditis, *Continue to #300*
❐ Multicentric Castleman's disease, *Continue to #350*
❐ Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD), *Continue to #400*
❐ Schnitzler syndrome, *Continue to #450*
❐ Gout flares, *Continue to #500*
❐ Pseudogout (also known as calcium pyrophosphate deposition disease) flares, *Continue to #500*
❐ Polyarticular juvenile idiopathic arthritis, *No Further Questions*
❐ Deficiency of interleukin-1 receptor antagonist (DIRA), *Continue to #550*
❐ Other Oncology Indication, *No Further Questions*
❐ Other, *No Further Questions*

Rheumatoid Arthritis

100. Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)?

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❒ Yes, *Continue to #101*
❒ No, *Continue to #101*

101. Is the patient an adult?
❒ Yes, *Continue to #102*
❒ No, *Continue to #102*

102. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to #103*
❒ No, *Continue to #103*

Continuation of Therapy

103. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #104*
❒ No, *Continue to #107*

104. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #107*
❒ No, *Continue to #105*
❒ Unknown, *Continue to #107*

105. Has the patient achieved or maintained positive clinical response since starting treatment with the requested drug?
❒ Yes, *Continue to #106*
❒ No, *Continue to #106*

106. 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?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Initial Therapy

Prior treatment with another biologic or targeted synthetic drug

107. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) that is indicated for moderately to severely active rheumatoid arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?
❒ Yes, *No Further Questions*
❒ No, *Continue to #108*

Requirements regarding prior therapy

108. 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?
❒ Yes, *Continue to #110*
❒ No, *Continue to #109*

109. 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)?
❒ Yes, *Continue to #110*
❒ No, *Continue to #110*

110. 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?
❒ Yes, *No Further Questions*
❒ No, *Continue to #111*

111. Has the patient experienced an intolerance to methotrexate?
❒ Yes, *No Further Questions*
❒ No, *Continue to #112*

112. Does the patient have a contraindication to methotrexate?
❒ Yes, *Continue to #113*
❒ No, *Continue to #113*

113. Please indicate the contraindication
❒ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*
❒ Drug interaction, *No Further Questions*
❒ Risk of treatment-related toxicity, *No Further Questions*
❒ Pregnancy or currently planning pregnancy, *No Further Questions*
❒ Breastfeeding, *No Further Questions*
❒ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *No Further Questions*
❒ Hypersensitivity, *No Further Questions*
❒ History of intolerance or adverse event, *No Further Questions*
❒ Other, *No Further Questions*

Adult-Onset Still's Disease

150. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to #151*
❒ No, *Continue to #151*

Continuation of Therapy

151. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #152*
❒ No, *Continue to #155*

152. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #155*
❒ No, *Continue to #153*
❒ Unknown, *Continue to #155*

153. 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, *Continue to #154*
❒ No, *Continue to #154*

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154. Which of the following has the patient experienced an improvement in from baseline?
❒ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion), *No Further Questions*
❒ Number of joints with limitation of movement, *No Further Questions*
❒ Functional ability, *No Further Questions*
❒ Systemic symptoms (e.g., fevers, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis), *No Further Questions*
❒ None of the above, *No Further Questions*

Initial Therapy

Prior treatment with another biologic drug

155. Has the patient ever received or is currently receiving a biologic indicated for active adult-onset Still's disease (excluding receiving the drug via samples or a manufacturer's patient assistance program)?
❒ Yes, *No Further Questions*
❒ No, *Continue to #156*

Requirements regarding prior therapy

156. Does the patient have active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or sore throat)?
❒ Yes, *Continue to #157*
❒ No, *Continue to #157*

157. 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 Further Questions*
❒ No, *No Further Questions*

Systemic Juvenile Idiopathic Arthritis

200. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to #201*
❒ No, *Continue to #201*

Continuation of Therapy

201. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #202*
❒ No, *Continue to #205*

202. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #205*
❒ No, *Continue to #203*
❒ Unknown, *Continue to #205*

203. Has the patient achieved 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, *Continue to #204*

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❒ No, *Continue to #204*

204. Which of the following has the patient experienced an improvement in from baseline?
❒ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion), *No Further Questions*
❒ Number of joints with limitation of movement, *No Further Questions*
❒ Functional ability, *No Further Questions*
❒ Systemic features (e.g., fevers, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis), *No Further Questions*
❒ None of the above, *No Further Questions*

Initial Therapy

205. Has the patient been diagnosed with active systemic juvenile idiopathic arthritis (sJIA)?
❒ Yes, *Continue to #206*
❒ No, *Continue to #206*

Prior treatment with another biologic drug

206. Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for active systemic juvenile idiopathic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?
❒ Yes, *No Further Questions*
❒ No, *Continue to #207*

Requirements regarding prior therapy

207. Does the patient have active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)?
❒ Yes, *Continue to #208*
❒ No, *Continue to #208*

208. Has the patient experienced an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or systemic glucocorticoids?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

250. Is the requested drug being prescribed by or in consultation with a rheumatologist or immunologist?
❒ Yes, *Continue to #251*
❒ No, *Continue to #251*

Continuation of Therapy

251. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #252*
❒ No, *No Further Questions*

252. Has the patient achieved 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, *Continue to #253*

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❒ No, *Continue to #253*

253. Which of the following has the patient experienced an improvement in from baseline?
❒ Fever, *No Further Questions*
❒ Skin rash, *No Further Questions*
❒ Joint pain and/or inflammation, *No Further Questions*
❒ Central nervous system (CNS) symptoms (e.g., meningitis, headache, cerebral atrophy, uveitis, hearing loss), *No Further Questions*
❒ Inflammatory markers (e.g., serum amyloid A [SAA], C-reactive protein [CRP], erythrocyte sedimentation rate [ESR]), *No Further Questions*
❒ None of the above, *No Further Questions*

Recurrent Pericarditis

300. Is the requested drug being prescribed by or in consultation with a cardiologist, rheumatologist, or immunologist
❒ Yes, *Continue to #301*
❒ No, *Continue to #301*

Continuation of Therapy

301. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #302*
❒ No, *Continue to #310*

302. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #310*
❒ No, *Continue to #303*
❒ Unknown, *Continue to #310*

303. Has the patient achieved or maintained a positive clinical response as evidenced by decreased recurrence of pericarditis?
❒ Yes, *No Further Questions*
❒ No, *Continue to #304*

304. Has the patient achieved 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, *Continue to #305*
❒ No, *Continue to #305*

305. Which of the following has the patient experienced an improvement in?
❒ Pericarditic or pleuritic chest pain, *No Further Questions*
❒ Pericardial or pleural rubs, *No Further Questions*
❒ Findings on electrocardiogram (ECG), *No Further Questions*
❒ Pericardial effusion, *No Further Questions*
❒ C-reactive protein (CRP), *No Further Questions*
❒ None of the above, *No Further Questions*

Initial Therapy

310. Has the patient had at least two episodes of pericarditis?

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❒ Yes, *Continue to #311*
❒ No, *Continue to #311*

311. Has the patient failed at least 2 agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Multicentric Castleman's disease

350. Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
❒ Yes, *Continue to #351*
❒ No, *Continue to #351*

351. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #352*
❒ No, *Continue to #354*

Continuation of Therapy

352. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #354*
❒ No, *Continue to #353*
❒ Unknown, *Continue to #354*

353. Has the patient experienced disease progression or an unacceptable toxicity?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Initial Therapy

Requirements regarding prior therapy (new starts)

354. Will the requested drug be used as a single agent?
❒ Yes, *Continue to #355*
❒ No, *Continue to #355*

355. Has the disease progressed following treatment of relapsed, refractory, or progressive disease?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

400. Is the requested drug being prescribed by or in consultation with a rheumatologist or immunologist?
❒ Yes, *Continue to #401*
❒ No, *Continue to #401*

401. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #402*
❒ No, *Continue to #410*

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Continuation of Therapy

402. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #410*
❒ No, *Continue to #403*
❒ Unknown, *Continue to #410*

403. Has the patient achieved 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 Further Questions*
❒ No, *No Further Questions*

Initial Therapy

New starts

410. Has the patient had active flares within the last 6 months?
❒ Yes, *Continue to #411*
❒ No, *Continue to #411*

411. What is the patient's Physician's Global Assessment (PGA) score?
❒ Less than 2, *Continue to #412*
❒ 2 or greater, *No Further Questions*
❒ Unknown, *Continue to #412*

412. What is the patient's C-reactive protein (CRP) level in mg/L?
❒ 10 mg/L or less, *No Further Questions*
❒ Greater than 10 mg/L, *No Further Questions*
❒ Unknown, *No Further Questions*

Schnitzler's syndrome

450. Is the requested drug being prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist?
❒ Yes, *Continue to #451*
❒ No, *Continue to #451*

451. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #452*
❒ No, *Continue to #460*

Continuation of Therapy

452. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #460*
❒ No, *Continue to #453*
❒ Unknown, *Continue to #460*

453. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or

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improvement in signs and symptoms of the condition since starting treatment with the requested drug?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Initial Therapy

New starts

460. Does the patient have an urticarial rash and monoclonal IgM (or IgG) gammopathy?
❒ Yes, *Continue to #461*
❒ No, *Continue to #461*

461. Does the patient have at least 2 of the following signs and symptoms?
- Fever
- Joint pain or inflammation
- Bone pain
- Lymphadenopathy
- Hepatomegaly or splenomegaly
- Leukocytosis
- Elevated erythrocyte sedimentation rate (ESR)
- Abnormalities on bone morphological study (e.g., increased bone density)

❒ Yes, *Continue to #462*
❒ No, *Continue to #462*

462. 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, hypocomplementemic urticarial vasculitis, acquired C1 inhibitor deficiency and cryoglobulinemia?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Gout/Pseudogout flares

500. Is the requested drug being requested for the treatment of flares for gout or pseudogout (also known as calcium pyrophosphate deposition disease)?
❒ Yes, *Continue to #501*
❒ No, *Continue to #501*

501. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to #502*
❒ No, *Continue to #502*

502. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #503*
❒ No, *Continue to #510*

Continuation of Therapy

503. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #510*

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❒ No, *Continue to #504*
❒ Unknown, *Continue to #510*

504. Has the patient achieved 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 Further Questions*
❒ No, *No Further Questions*

Initial Therapy

510. Has the patient experienced at least three flares in the last 12 months?
❒ Yes, *Continue to #511*
❒ No, *Continue to #511*

511. Has the patient had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or has an intolerance or contraindication to NSAIDs?
❒ Yes, *Continue to #512*
❒ No, *Continue to #512*

512. Has the patient had an inadequate response to colchicine or has an intolerance or contraindication to colchicine?
❒ Yes, *Continue to #513*
❒ No, *Continue to #513*

513. Has the patient had an inadequate response to corticosteroids or an intolerance or contraindication to corticosteroids?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

550. Is the requested drug being prescribed by or in consultation with a rheumatologist or immunologist?
❒ Yes, *Continue to #551*
❒ No, *Continue to #551*

551. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #552*
❒ No, *Continue to #554*

Continuation of Therapy

552. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to #554*
❒ No, *Continue to #553*
❒ Unknown, *Continue to #5554*

553. Has the patient achieved 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 Further Questions*
❒ No, *No Further Questions*

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Initial Therapy

554. Has the diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) been genetically confirmed?
❒ Yes, *Continue to #555*
❒ No, *Continue to #555*

555. Does the patient have DIRA due to IL1RN mutations? ***ACTION REQUIRED**: If 'Yes', please attach documentation of IL1RN mutation status*
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

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