Arcalyst

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.

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:** _____
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? _____

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

 Arcalyst HMSACOM C12374-A – 01/2024.

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 #100*

❒ No, *Continue to #3*

3. 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, *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 #100*

❒ 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 #100*

❒ Patient has latent TB and treatment for latent TB has been completed, *Continue to #100*

❒ Patient has latent TB and treatment for latent TB has not been initiated, *No Further Questions*

❒ Patient has active TB, *No Further Questions*

Diagnosis

100. What is the patient's diagnosis?

❒ Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), *Continue to #101*

❒ Deficiency of interleukin-1 receptor antagonist (DIRA), *Continue to #200*

❒ Recurrent pericarditis, *Continue to #300*

❒ Other, *No Further Questions*

Cryopyrin-Associated Periodic Syndromes (CAPS)

101. Is the patient 12 years of age or older?

❒ Yes, *Continue to #102*

❒ No, *No Further Questions*

102. Is the requested drug prescribed by or in consultation with a rheumatologist or immunologist?

❒ Yes, *Continue to #103*

❒ No, *Continue to #103*

103. Is this request for continuation of therapy with Arcalyst?

❒ Yes, *Continue to #104*

❒ No, *Continue to #106*

Continuation of Therapy

104. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to #106*

❒ No, *Continue to #105*

❒ Unknown, *Continue to #106*

105. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms since starting treatment with the requested drug? ***Action Required***: If yes, please attach documentation (e.g., chart notes or medical record) supporting a beneficial response to therapy

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Initial Therapy

106. Which is the patient's diagnosis? ***Action Required***: Please attach documentation supporting the diagnosis.For CAPS, please submit the results of molecular genetic testing demonstrating a mutation in the NLRP3 gene (also known as CIAS1) (applicable to FCAS and MWS).If genetic testing is not available/no mutation identified, chart notes/medical record must be submitted

❒ Familial cold auto-inflammatory syndrome (FCAS), *Continue to #107*

❒ Muckle-Wells syndrome (MWS), *Continue to #108*

❒ None, *No Further Questions*

107. Does the patient have classic signs and symptoms of familial cold auto-inflammatory syndrome (FCAS) (i.e., recurrent, intermittent fever and rash that were often exacerbated by exposure to generalized cool ambient temperature)?

❒ Yes, *Continue to #109*

❒ No, *Continue to #109*

108. Does the patient have classic signs and symptoms of Muckle-Wells syndrome (MWS) (i.e., chronic fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature)?

❒ Yes, *Continue to #109*

❒ No, *Continue to #109*

109. Does the patient have functional impairment limiting the activities of daily living?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Deficiency of interleukin-1 receptor antagonist (DIRA)

200. Does the patient weigh 10 kg or more?

❒ Yes, *Continue to #201*

❒ No, *No Further Questions*

201. Is the requested drug being prescribed by or in consultation with a rheumatologist or immunologist?

❒ Yes, *Continue to #202*

❒ No, *Continue to #202*

202. Is this request for continuation of therapy with Arcalyst?

❒ Yes, *Continue to #203*

❒ No, *Continue to #205*

Continuation of Therapy

203. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to #205*

❒ No, *Continue to #204*

❒ Unknown, *Continue to #205*

204. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms since starting treatment with the requested drug?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Initial Therapy

205. Does the patient have loss-of-function IL1RN mutations? ***ACTION REQUIRED****: If 'Yes', please attach documentation of IL1RN mutation status*

❒ Yes, *Continue to #206*

❒ No, *Continue to #206*

206. Will the requested drug be used for maintenance of remission following treatment with Kineret (anakinra)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Recurrent pericarditis

300. Is the patient 12 years of age or older?

❒ Yes, *Continue to #301*

❒ No, *No Further Questions*

301. Is the requested drug being prescribed by or in consultation with a cardiologist, rheumatologist, or immunologist?

❒ Yes, *Continue to #302*

❒ No, *Continue to #302*

302. Is this request for continuation of therapy with Arcalyst?

❒ Yes, *Continue to #303*

❒ No, *Continue to #310*

Continuation of Therapy

303. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to #310*

❒ No, *Continue to #304*

❒ Unknown, *Continue to #310*

304. Has the patient achieved or maintained positive clinical response since starting treatment with the requested drug?

❒ Yes, *Continue to #305*

❒ No, *Continue to #305*

305. Has the patient experienced a decreased recurrence of pericarditis? ***ACTION REQUIRED****: Please attach chart notes or medical record documentation supporting positive clinical response*

❒ Yes, *No Further Questions*

❒ No, *Continue to #306*

306. Has the patient experienced an improvement in signs and symptoms of the condition?

❒ Yes, *Continue to #307*

❒ No, *Continue to #307*

307. 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, *No Further Questions*

❒ Pericardial rubs, *No Further Questions*

❒ 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?

❒ Yes, *Continue to #311*

❒ No, *Continue to #311*

311. Has the patient failed at least two 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 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