



PRIOR AUTHORIZATION REQUEST

Arcalyst

Patient Information:

| | |
|-------------------|--|
| Name: | |
| Member ID: | |
| Address: | |
| City, State, Zip: | |
| Date of Birth: | |

Prescriber Information:

| | |
|-------------------|--|
| Name: | |
| NPI: | |
| Phone Number: | |
| Fax Number: | |
| Address: | |
| City, State, Zip: | |

Requested Medication

| | |
|-----------------------------|--|
| Rx Name: | |
| Rx Strength: | |
| Rx Quantity: | |
| Rx Frequency: | |
| Rx Route of Administration: | |
| Diagnosis and ICD Code: | |

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for ALL PA requests.

| | | | |
|---|--|-----|----|
| 1 | Will the requested medication be used in combination with another biologic agent for an inflammatory condition (for example, Cimzia, an etanercept product (Enbrel, biosimilars), an adalimumab product (Humira, biosimilars), Simponi (Aria or SC), an infliximab product (Remicade, biosimilars), Actemra (SC or IV), Kevzara, Orencia (SC or IV), a rituximab product (Rituxan, biosimilars), Kineret, Stelara (SC or IV), Siliq, Cosentyx, Taltz, Ilumya, Tremfya, Skyrizi, Entyvio)? [If yes, no further questions.] | Yes | No |
| 2 | What is the diagnosis or indication? [] Cryopyrin-Associated Periodic Syndromes (including familial cold autoinflammatory syndrome, Muckle- Wells Syndrome, and neonatal onset multisystem inflammatory | | |

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PRIOR AUTHORIZATION REQUEST

disease or chronic infantile neurological cutaneous and articular syndrome) (If checked, go to 3)

☐ Deficiency of interleukin-1 receptor antagonist (If checked, go to 9)

☐ Pericarditis (If checked, go to 17)

☐ All other indications or diagnoses (If checked, no further questions)

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| 3 | Is the patient currently receiving the requested medication? [If no, skip to question 7.] | Yes | No |
|---|--|-----|----|

| | | | |
|---|--|-----|----|
| 4 | Has the patient already received at least 6 months of therapy with the requested medication? [If no, skip to question 7.] | Yes | No |
|---|--|-----|----|

[NOTE: Answer 'No' if the patient has received less than 6 months of therapy or if the patient is restarting therapy with the requested medication.]

| | | | |
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| 5 | When assessed by at least one objective measure, has the patient experienced a beneficial clinical response from baseline (prior to initiating the requested medication)? [If yes, no further questions.] | Yes | No |
|---|--|-----|----|

[NOTE: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (for example, C-reactive protein, amyloid A), reduction in proteinuria, and/or stabilization of serum creatinine.]

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| 6 | Compared with baseline (prior to receiving the requested medication), has the patient experienced an improvement in at least one symptom, such as such as fewer cold-induced attacks, less joint pain/tenderness, stiffness, or swelling, decreased fatigue, improved function or activities of daily living? [No further questions.] | Yes | No |
|---|--|-----|----|

| | | | |
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| 7 | Is the patient greater than or equal to 12 year(s) of age? [If no, no further questions.] | Yes | No |
|---|--|-----|----|

| | | | |
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| 8 | Is the requested medication being prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist? [No further questions.] | Yes | No |
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| 9 | Is the patient currently receiving the requested medication? [If no, skip to question 13.] | Yes | No |
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| 10 | Has the patient already received at least 6 months of therapy with the requested medication? [If no, skip to question 13.] | Yes | No |
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| 11 | When assessed by at least one objective measure, has the patient experienced a beneficial clinical response from baseline (prior to initiating the requested medication)? [If yes, no further questions.] | Yes | No |
|----|--|-----|----|

[NOTE: Examples of objective measures include improvement in rash or skin

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PRIOR AUTHORIZATION REQUEST

manifestations, clinically significant improvement or normalization of serum markers (for example, C-reactive protein, erythrocyte sedimentation rate), reduction in proteinuria, and/or stabilization of serum creatinine.]

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| 12 | Compared with baseline (prior to receiving the requested medication), has the patient experienced an improvement in at least one symptom, such as such as improvement of skin or bone symptoms, less joint pain/tenderness, stiffness, or swelling? [No further questions.] | Yes | No |
| 13 | Is the patient 10 kilograms (22 pounds) or greater? [If no, no further questions.] | Yes | No |
| 14 | Has genetic testing confirmed a mutation in the IL1RN gene? [If no, no further questions.] | Yes | No |
| 15 | Has the patient previously demonstrated a clinical benefit with Kineret (anakinra subcutaneous injection)? [If no, no further questions.] | Yes | No |
| [NOTE: Examples of a clinical response with Kineret include normalized acute phase reactants; resolution of fever, skin rash, and bone pain; and reduced dosage of corticosteroids.] | | | |
| 16 | Is the requested medication being prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders? [No further questions.] | Yes | No |
| 17 | Is the patient currently receiving the requested medication? [If no, skip to question 21.] | Yes | No |
| 18 | Has the patient been established on this medication for at least 3 months? [If no, skip to question 21.] | Yes | No |
| [NOTE: Answer 'No' if the patient has received less than 90 days of therapy or if the patient is restarting therapy with the requested medication.] | | | |
| 19 | When assessed by at least one objective measure, has the patient experienced a beneficial clinical response from baseline (prior to initiating the requested medication)? [If yes, no further questions.] | Yes | No |
| [NOTE: Examples of objective measures include normalization of inflammatory biomarkers such as erythrocyte sedimentation rate and/or C-reactive protein, continued resolution of fever.] | | | |
| 20 | Compared with baseline (prior to receiving the requested medication), has the patient experienced an improvement in at least one symptom, such as resolution of chest pain or pericarditis pain? [No further questions.] | Yes | No |
| 21 | Is the patient greater than or equal to 12 year(s) of age? [If no, no further questions.] | Yes | No |

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PRIOR AUTHORIZATION REQUEST

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| 22 | Does the patient have recurrent pericarditis? [If no, no further questions.] | Yes | No |
| 23 | Prior to starting treatment with the requested medication, did the patient have a history of at least three episodes of pericarditis? [If no, no further questions.] | Yes | No |
| 24 | For the current episode, is the patient receiving standard treatment? [If yes, skip to question 26.] | Yes | No |
| [NOTE: Standard treatments for pericarditis include nonsteroidal anti-inflammatory drug(s) [NSAIDs], colchicine, and/or systemic corticosteroids.] | | | |
| 25 | Is standard treatment contraindicated? [If no, no further questions.] | Yes | No |
| [NOTE: Standard treatments for pericarditis include nonsteroidal anti-inflammatory drug(s) [NSAIDs], colchicine, and/or systemic corticosteroids.] | | | |
| 26 | Is the requested medication being prescribed by or in consultation with a cardiologist or rheumatologist? | Yes | No |

Please document the diagnoses, symptoms, and/or any other information important to this review:

SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

FAX COMPLETED FORM TO: 1-833-896-0656

Disclaimer: An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

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