

Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Rilonacept (Arcalyst)

Notes:

- Quantity Limits: Yes
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **rilonacept (Arcalyst)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

Non-formulary **rilonacept (Arcalyst)** will be covered on the prescription drug benefit when the following criteria are met:

1. Prescriber is a cardiologist or a rheumatologist and patient has a history of Recurrent Pericarditis (RP):
 - Patient is 12 years of age or older
 - Patient has had at least 2 recurrences of pericarditis (3 episodes overall)
 - Patient has tried and failed/intolerant to the following:
 - Non-steroidal anti-inflammatory medications (NSAIDs)
 - Colchicine
 - Oral glucocorticoids
 - Patient has tried and failed/intolerant to at least 3 months of anakinra (criteria based)
 - Patient has C-reactive protein level greater than or equal to 1 mg/dL in the last 7 days while on current maximally tolerated therapy, including anakinra
2. Prescriber is a rheumatologist and patient has a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) [including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)]:
 - Patient is 12 years of age or older
 - Patient has tried and failed/intolerant to the following:
 - Anakinra (criteria based)
 - Canakinumab (criteria based)

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3. Prescriber is a rheumatologist and patient has a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA):
 - Patient is 3 years of age or older
 - Patient weighs 10 kg or more
 - Patient has tried and failed/intolerant to anakinra (criteria based)

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