Rilonacept (Arcalyst)

Coverage Criteria for CAPS and DIRA:
Arcalyst is reserved for patients meeting the following criteria:

1. Patient has been diagnosed with one of the following:
    a. Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS); or
    b. Deficiency of interleukin-1 receptor antagonist (DIRA) confirmed with a mutation in the IL1RN gene
2. Patient is unable to use Kineret (due to a documented allergic reaction or medical contraindication). Medical literature documenting clinical effectiveness superiority of Arcalyst over Kineret is required; and,
3. When prescribed by a specialist; and,
4. The patient and/or guardian has attested that they will adhere to the treatment plan; and
5. When prescribed according to an FDA-approved maintenance regimen of 160 mg weekly.

Coverage Duration:
Initial approvals will be granted for a 6 month duration.
Reauthorizations will be granted for a 12 month duration.

Renewal Criteria:

1. Patient continues to meet criteria above, and
2. Medical chart documentation has been provided that demonstrate the patient has been seen within the past 12 months
3. Medical chart documentation has been provided that demonstrate markers of disease are improved by therapy. These include but may not be limited to reduced symptoms of disease and inflammatory markers, including serum C-reactive protein and amyloid A for CAPS, and normalized acute phase reactants; resolution of fever, skin rash, and bone pain; and/or reduced dosage of corticosteroids for DIRA.

Coverage Criteria for Recurrent Pericarditis:
Arcalyst is reserved for patients meeting the following criteria:

1. Prescribed by cardiologist; and,
2. Patient has recurrent pericarditis, defined as 3 or more episodes of symptomatic pericarditis in one year, each after an at least four- to six-week symptom-free interval; and,
3. Patient has an inflammatory phenotype, characterized by the presence of one or more of signs of an inflammatory process when presenting with a recurrence: fever, elevated CRP, elevated WBC count, elevated ESR, pericardial LGE on CMR, or pericardial contrast enhancement on CT; and,
4. Patient has no active infections, including but not limited to bacterial infections, fungal infections, viral infections, HIV, or TB; and,
5. Patient has tried and failed or has medical contraindications to the following therapies concurrently:
    a. nonsteroidal anti-inflammatory drugs for at duration of at least 3 months; and,
    b. colchicine for a duration of at least 6 months; and,

c. corticosteroids for at least 2 months; and,

6. The prescriber attests that ongoing immunosuppressive therapy with Arcalyst is more appropriate for the patient than pericardiectomy; and,
7. The patient has tried and failed or has medical contraindications to Kineret; and,
8. Arcalyst has been prescribed at the FDA-approved dosing.

Coverage Duration:
Initial authorizations and renewals will be for a 6 month duration

Renewal Criteria for Recurrent Pericarditis:

1. The patient continues to meet the criteria above; and,
2. The prescriber attests that ongoing immunosuppressive therapy with Arcalyst continues to be more appropriate for the patient than pericardiectomy; and,
3. Chart documentation is provided demonstrating continued clinical benefit of Arcalyst (e.g reduction in glucocorticoid use, reduction in recurrence of pericarditis symptoms); and,
4. The patient has been seen by the prescribing provider within the past 12 months.