

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<b>DRUG NAME</b>	<b>Arcalyst (Riloncept)</b>
BILLING CODE	J2793
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Arcalyst is an interleukin 1 (IL-1) antagonist indicated for Cryopyrin-Associated Periodic Syndromes (CAPS), Deficiency of IL-1 Receptor Antagonist (DIRA), and recurrent pericarditis.

CAPS refer to rare genetic syndromes generally caused by mutations in the NLRP-3 [Nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]). Mutations in NLRP-3 result in an overactive inflammasome leading to an excessive release of activated IL-1β.

DIRA is an auto-inflammatory, autosomal recessive disorder caused by loss of function mutations in the IL1RN gene, which encodes IL-1 receptor antagonist (IL-1RAcP).

For **reauthorization**:

1. Chart notes demonstrate positive clinical response including decreased inflammatory marker values and symptom improvement.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## **Deficiency of IL-1 Receptor Antagonist (DIRA)**

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a rheumatologist, dermatologist, or geneticist; AND
2. Member has a diagnosis of DIRA confirmed by ALL of the following:
  - a) Genetic testing shows IL1RN mutation,
  - b) Member has baseline symptoms of skin and/or bone inflammation,
  - c) Inflammatory markers (erythrocyte sedimentation rate [ESR], C-reactive protein [CRP]) are elevated at baseline; AND
3. Member has had a negative tuberculosis test within the past 12 months.
4. **Dosage allowed/Quantity limit:**  
Adults: 320 mg (160 mg at 2 different sites on the same day) subQ once weekly  
Pediatric

