Rilonacept (Arcalyst®)

Place of Service
- Office Administration
- Home Infusion Administration
- Outpatient Facility Administration
- Infusion Center Administration
- Self-Administration - May be covered under the pharmacy benefit

HCPCS: J2793 per 1mg

Condition listed in Policy (see criteria for details)
- Cryopyrin-associated periodic syndromes (CAPS)
- Deficiency of interleukin-1 receptor antagonist (DIRA)
- Recurrent pericarditis

AHFS therapeutic class: Miscellaneous therapeutic agents
Mechanism of action: Interleukin-1 blocker

(1) Special Instructions and pertinent Information
If member has a Prescription Benefit, please refer cases to Pharmacy Services for prior authorization.

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax. Please include medical rationale why medication cannot be home self-administered.

(2) Prior Authorization/Medical Review is required for the following condition(s)
All requests for Arcalyst® (rilonacept) must be sent for clinical review and receive authorization prior to drug administration or claim payment.
Cryopyrin-associated periodic syndromes (CAPS)
1. Diagnosis of CAPS, including familial cold autoinflammatory syndrome (FCAS) and Muckle Wells syndrome (MWS), **AND**
2. Patient is 12 years of age or older

**Covered Doses**
Initial loading dose: Up to 320 mg by subcutaneous injection (160 mg x two injections given on the same day)

Maintenance dose: Up to 160 mg by subcutaneous injection once weekly

**Coverage Period**
Indefinite

**ICD-10:**
M04.2

Deficiency of interleukin-1 receptor antagonist (DIRA)
1. Patient experienced clinical benefit from treatment with anakinra, **AND**
2. Not being used in combination with anakinra

**Covered Doses**
Up to 4.4 mg/kg (maximum of 320 mg) subcutaneous injection once weekly

**Coverage Period**
Indefinite

**ICD-10:**
M04.8

Recurrent pericarditis
1. Recommended by a cardiologist, **AND**
2. Patient is 12 years of age or older, **AND**
3. One of the following conditions is met:
   a. Patient has experienced an inadequate response, intolerance, or contraindication to colchicine in combination with NSAIDs, or
   b. Patient is steroid-dependent, or inadequate response, intolerance, or contraindication to corticosteroids

**Covered Doses**
Initial loading dose: Up to 320 mg by subcutaneous injection (160 mg x two injections given on the same day)

Maintenance dose: Up to 160 mg by subcutaneous injection once weekly

**Coverage Period**
Indefinite
ICD-10:
I30.0-I32

(3) The following condition(s) **DO NOT** require Prior Authorization/Preservice
All requests for Arcalyst® (rilonacept) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is **NOT** medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:
220 mg lyophilized powder for reconstitution (single-use 20 mL vial)

(6) References
- AHFS®. Available by subscription at http://www.lexi.com

(7) Policy Update
Date of last revision: 2Q2021
Date of next review: 1Q2022
Changes from previous policy version:
- New indication and Section (2): Added coverage for recurrent pericarditis
  **Rationale:** In March 2021, FDA approved Arcalyst for treatment of RP and reduction in risk of recurrence in adults and children 12 years and older; 2020 ACC guidelines recommendations for RP treatment.