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

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(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
- Arcalyst® (rilonacept) [Prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 5/2021.
- Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of Acute and Recurrent Pericarditis: JACC State-of-the-Art Review. Journal of American College of Cardiology. 2020 Jan 7;75(1):76-92.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

(7) Policy Update

Date of last review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee