Clinical Policy: Rilonacept (Arcalyst)

Reference Number: PA.CP.PHAR.266
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

Description
Rilonacept (Arcalyst®) is an interleukin-1 blocker.

FDA approved indication
Arcalyst (rilonacept) is an interleukin-1 blocker indicated for the treatment of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS) in adults and children 12 and older.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of PA Health and Wellness® that Arcalyst is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Cryopyrin Associated Periodic Syndromes (must meet all)**:**

1. Diagnosis of FCAS or MWS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 12 years;
4. Dose does not exceed a loading dose of 320mg (as two injections) and once weekly dosing of 160mg (as a single injection).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53.

II. Continued Approval

A. Cryopyrin-Associated Periodic Syndromes (must meet all)**:**

1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or Continuity of Care policy applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed once weekly dosing of 160 mg (as a single injection).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

C. Currently receiving medication via Pennsylvania Health and Wellness benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies and documentation supports positive response to therapy; or

Approval duration: Duration of request or 6 months (whichever is less); or

1. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CAPS: Cryopyrin-Associated Periodic Syndromes
FCAS: Familial Cold Autoinflammatory Syndrome
FDA: Food and Drug Administration
MWS: Muckle-Wells Syndrome

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- Three related conditions make up the broader disease known as CAPS: FCAS, MWS, and neonatal-onset multisystem inflammatory disease (NOMID), also known as chronic infantile neurologic cutaneous articular syndrome (CINCA). Arcalyst is not FDA-approved for use in patients with NOMID/CINCA.
- Concomitant administration of Arcalyst with tumor necrosis factor (TNF) inhibitors (e.g., Enbrel, Humira, or Remicade) and interleukin-1 blocking agents (e.g., Kineret) is not recommended because this may increase the risk of serious infections.
- Examples of positive response to therapy include reduction/normalization of: C-reactive protein levels, serum amyloid A levels, flare frequency, or severity and duration of symptoms (e.g., joint pain, rash, fever/chills, eye pain, fatigue).
- Do not initiate treatment with Arcalyst in patients with active or chronic infections.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CAPS (FCAS, MWS)	18 yrs and older: 320 mg SC loading dose followed by 160 mg SC once weekly 12 to 17 yrs: 4.4 mg/kg SC loading dose (maximum 320 mg) followed by 2.2 mg/kg (maximum of 160 mg) SC once weekly	320 mg loading dose; 160 mg weekly maintenance dose

V. Product Availability

Drug	Availability
Rilonacept (Arcalyst)	Single-use vial: 220 mg

VI. References

1. Arcalyst Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2016. Available at https://www.regeneron.com/sites/default/files/Arcalyst_FPI.pdf. Accessed February 26, 2019.

2. Hoffman, HM, Throne ML, Amar NJ, et al. Efficacy and safety of rilonacept (interleukin-1 trap) in patients with cryopyrin-associated periodic syndromes. Arthritis and Rheumatism. 2008;58(8): 2443-2452.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2793	Injection, rilonacept, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: references reviewed and updated.		
2Q 2019 annual review: references reviewed and updated.	04/19	