Clinical Policy: Rilonacept (Arcalyst)

Reference Number: ERX.SPA.108
Effective Date: 10.01.16
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

FDA Approved Indication(s)
Arcalyst is indicated for the treatment of cryopyrin-associated periodic syndromes (CAPS), including familial cold auto-inflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS) in adults and children 12 and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Arcalyst is **medically necessary** when 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 320 mg (as two injections) and once weekly dosing of 160 mg (as a single injection).

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Cryopyrin-Associated Periodic Syndromes (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. 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 IL-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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CAPS (FCAS, MWS)	Age ≥ 18 years: 320 mg SC loading dose followed by 160 mg SC once weekly Age 12 to 17 years: 4.4 mg/kg SC loading dose followed by 2.2 mg/kg SC once weekly	Loading dose: 320 mg; Maintenance dose: 160 mg weekly

VI. Product Availability

Single-use vial for reconstitution: 220 mg (each reconstituted vial delivers 160 mg)

VII. 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, 2020.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from USS.SPMN.09 Cryopryin-Associated Periodic Syndromes (CAPS) Treatments and converted to new template. Removed all safety criteria. Modified approval duration to 6 months for initial and 12 months for re-auth.	08.16	09.16
Converted to new template. Section II: added examples of CAPS related symptoms to assess on continued authorization.	07.17	08.17
4Q17 Annual Review Aligned diagnostic criteria for CAPS with Ilaris policy.	09.29.17	11.17
2Q 2018 annual review: no significant changes; moved examples of positive response to therapy to Appendix C: General Information; references reviewed and updated.	02.27.18	05.18
4Q 2018 annual review: no significant changes; references reviewed and updated.	09.04.18	11.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.26.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.