Arcalyst (rilonacept)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Quantity Limit
Arcalyst (rilonacept) 160 mg/2 mL (220 mg) single-use vial*	4 vials per 28 days

*Initiation of therapy for Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), or Recurrent Pericarditis (RP): May approve 1 (one) additional vial (160 mg/2 mL) in the first 28 days (4 weeks) of treatment.
For the treatment of deficiency of interleukin-1 receptor antagonist (DIRA): May approve up to 8 vials per 28 days.

APPROVAL CRITERIA

Initial requests for Arcalyst (rilonacept) may be approved for the following:

I. Cryopyrin-associated periodic syndromes (CAPS) when each of the following criteria are met:
   A. Individual is 12 years of age or older with either of the following cryopyrin-associated periodic syndromes:
      1. Familial cold autoinflammatory syndromes; **OR**
      2. Muckle-Wells syndrome;

OR

II. Deficiency of Interleukin-1 Receptor Antagonist (DIRA) when each of the following criteria are met:
   A. Individual weighs at least 10 kilograms; **AND**
   B. DIRA is confirmed through IL1RN mutations; **AND**
   C. Disease is in remission from previous anakinra (Kineret) treatment;

OR

III. Recurrent Pericarditis (RP) when each of the following criteria are met:
   A. Individual is 12 years of age or older using for treatment of RP or reduction in risk of recurrence; **AND**
   B. Individual has a history of at least two pericarditis episodes (i.e. presents with at least the third episode) (Klein 2021).

Continuation requests for Arcalyst (rilonacept) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Arcalyst. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Arcalyst (rilonacept) may **not** be approved for i the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, other IL-1 inhibitors, IL-6 inhibitors, rituximab, or natalizumab; **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 7, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Klein AL, Imazio M, Cremer P, et al. RHAPSODY Investigators. Phase 3 Trial of Interleukin-1 Trap Rilonacept in Recurrent Pericarditis. N Engl J Med. 2021 Jan 7;384(1):31-41.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2022 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: October 4, 2022.
6. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 4, 2022.