

Prior Authorization DRUG Guidelines

Arcalyst (rilonacept)

Date Developed: 9/3/13 by Albert Reeves MD

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Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

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Arcalyst binds to IL-1 beta and to a lesser extent IL-1 alpha thus preventing their interactions with inflammatory cell surface receptors. This reduces the inflammatory response that results from under-production of the protein Cryopyrin due to a mutation in the NLRP-3 gene. Cryopyrin down-regulates production of IL-1.

Pre-Authorization Criteria: Cryopyrin-associated periodic syndromes (e.g. familial cold autoinflammatory syndrome; Muckle-Wells syndrome) in adults and children 12 years and older

Dosing: Adult

Cryopyrin-associated periodic syndromes: SubQ: Loading dose 320 mg given as 2 separate injections (160 mg each) on the same day at 2 different sites, followed by a once-weekly dose of 160 mg.

Note: Do not administer more frequently than once weekly.

Dosing: Pediatric

Cryopyrin-associated periodic syndromes: Children **≥12 years:** SubQ: Loading dose 4.4 mg/kg (maximum dose: 320 mg) given as 1-2 separate injections (maximum: 2 mL/injection; administer at 2 different sites if multiple injections are necessary) on the same day, followed by a once-weekly dose of 2.2 mg/kg (maximum dose: 160 mg).

Note: Do not administer more frequently than once weekly.

PRECAUTIONS:

predisposition to infection; may increase total cholesterol, HDL, LDL and triglycerides; patients should be brought up to date with all immunizations; live vaccines should not be given concurrently

DRUG INTERACTIONS: increased risk of infection if used with TNF-antagonists; enhanced immunosuppression and/or side effects if used with other immunosuppressants ; see product information for other drug interactions

REFERENCES

1. Goldback-Mansky R, Shroff SD, Wilson M, et al, "A Pilot Study to Evaluate the Safety and Efficacy of the Long-Acting Interleukin-1 Inhibitor Rilonacept (Interleukin-1 Trap) in Patients With Familial Cold Autoinflammatory Syndrome," *Arthritis Rheum*, 2008, 58(8):2432-42. [PubMed [18668591](#)]
2. Hoffman HM, Throne ML, Amar NJ, et al, "Efficacy and Safety of Rilonacept (Interleukin-1 Trap) in Patients With Cryopyrin-Associated Periodic Syndromes: Results From Two Sequential Placebo- Controlled Studies," *Arthritis Rheum*, 2008, 58(8):2443-52. [PubMed [18668535](#)]
3. Hoffman HM, Throne ML, Amar NJ, et al, "Long-Term Efficacy and Safety Profile of Rilonacept in the Treatment of Cryopyrin-Associated Periodic Syndromes: Results of a 72-Week Open-Label Extension Study," *Clin Ther*, 2012, 34(10):2091-103. [PubMed [23031624](#)]
4. Miyamae T, "Cryopyrin-Associated Periodic Syndromes: Diagnosis and Management," *Pediatr Drugs*, 2012, 14(2):109-17. [PubMed [22335455](#)]
5. Radin A, Marbury T, Osgood G, et al, "Safety and Pharmacokinetics of Subcutaneously Administered Rilonacept in Patients With Well-Controlled End-Stage Renal Disease (ESRD)," *J Clin Pharmacol*, 2010, 50(7):835-41. [PubMed [20035038](#)]

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