Pharmacy Drug Policy & Procedure

Policy Name:	Arcalyst (rilonacept)	Policy#:	2385P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Arcalyst (rilonacept).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Arcalyst (rilonacept) under the specialty medical benefit if the following criteria are met.

Criteria

1. Criteria for Coverage for Cryopyrin-Associated Periodic Syndromes (CAPS)

1.1 Diagnosis of CAPS

1.2 Diagnosis must be confirmed by genetic testing demonstrating a mutation in the NLRP3 gene and presence of specific clinical criteria

1.3 Age 12 years or older

1.4 Prescribed by or in consultation with a rheumatologist (musculoskeletal doctor), geneticist (gene doctor), or allergist/immunologist (immune system doctor)

2. Criteria for Coverage for Recurrent Pericarditis (long term heart inflammation)

2.1 Diagnosis of recurrent pericarditis as supported by ≥ 3 previous episodes

2.2 Age 12 years or older

2.3 Prescribed by or in consultation with a cardiologist (heart doctor) or rheumatologist (musculoskeletal doctor)

2.4 Patient is currently stable on standard of care (such as nonsteroidal anti-inflammatory drug(s) [NSAIDs], colchicine, and/or systemic corticosteroids)

3. Criteria for Coverage for Deficiency of the IL-1-Receptor Antagonist (DIRA)

3.1 Diagnosis of deficiency of the IL-1RN (DIRA) as supported by clinical criteria

3.2 Diagnosis confirmed by genetic testing supported mutation in the IL1RN gene

3.3 Patient weighs 10kg or more

3.4 Prescribed by or in consultation with a rheumatologist (musculoskeletal doctor), geneticist (gene doctor), or a physician specializing in the treatment of auto-inflammatory disorders

3.5 All other interleukin-1 blockers have been discontinued

4. Exclusion Criteria

4.1 Inadequate response to initial or previous rilonacept therapy

4.2 Health Alliance does not cover concurrent therapy with other immunomodulators based upon the possible increased risk for infections and other potential pharmacological interactions

5. Approval Time

5.1 Initial Authorization will be placed for 12 months

5.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

CPT Codes	
96365 - 96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)
HCPCS Codes	

J2793	Injection, rilonacept [Arcalyst]

References

1. Arcalyst (rilonacept) [prescribing information]. London, UK: Kiniksa Pharmaceuticals (UK) Ltd; May 2021.
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3. Miyamae T. Cryopyrin-Associated Periodic Syndromes: Diagnosis and Management. Pediatr Drugs. 2012;14(2):109-117.
4. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. N Engl J Med. 2021;384(1):31-41.
5. Chiabrando JG, Bonaventura A, Vecchie A, et al. Management of acute and recurrent pericarditis. J Am Coll Cardiol. 2020;75(1):76-92.
6. Aksentijevich I, Masters SL, Ferguson PJ, et al. An autoinflammatory disease with deficiency of the interleukin-1-receptor antagonist. N Engl J Med 2009; 360:2426.
7. Garg M, de Jesus AA, Chapelle D, et al. Rilonacept maintains long-term inflammatory remission in patients with deficiency of the IL-1 receptor antagonist. JCI Insight 2017; 2.

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