

Arcalyst (rilonacept)
Effective 01/01/2024

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

FDA-Approved Indications

- A. Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years of age and older.
- B. Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg.
- C. Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted when the following diagnosis-specific criteria is met:

A. Cryopyrin-associated periodic syndromes (CAPS)

Authorization may be granted for members 12 years of age or older for treatment of CAPS when both of the following criteria are met:

1. Member has a diagnosis of familial cold autoinflammatory syndrome (FCAS) with classic signs and symptoms (i.e., recurrent, intermittent fever and rash that were often exacerbated by exposure to generalized cool ambient temperature) or Muckle-Wells syndrome (MWS) with classic signs and symptoms (i.e., chronic fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature).
2. Member has functional impairment limiting the activities of daily living.

3. The medication must be prescribed by or in consultation with a rheumatologist or immunologist.

B. Deficiency of interleukin-1 receptor antagonist (DIRA)

Authorization may be granted for members weighing at least 10 kg for treatment of DIRA when both of the following criteria are met:

1. Member has *IL1RN* mutations confirmed by documentation of mutation status.
2. Arcalyst will be used for maintenance of remission following treatment with Kineret (anakinra).
3. The medication must be prescribed by or in consultation with a rheumatologist or immunologist.

C. Recurrent pericarditis

Authorization may be granted for members 12 years of age or older for treatment of recurrent pericarditis when both of the following criteria are met:

1. Member has had at least two episodes of pericarditis.
2. Member has failed at least 2 agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids) confirmed by chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
3. The medication must be prescribed by or in consultation with a cardiologist, rheumatologist, or immunologist.

Continuation of Therapy

A. Cryopyrin-associated periodic syndromes (CAPS)

Authorization may be granted for all members 12 years of age or older (including new members) who are using the requested medication for CAPS who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

B. Deficiency of interleukin-1 receptor antagonist (DIRA)

Authorization may be granted for all members weighing at least 10 kg (including new members) who are using the requested medication for DIRA and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

C. Recurrent pericarditis

Authorization may be granted for all members 12 years of age or older (including new members) who are using the requested medication for recurrent pericarditis and who achieve or maintain a positive clinical response as evidenced by decreased recurrence of pericarditis or improvement in signs and symptoms of the condition when there is improvement in any of the following:

1. Pericarditic chest pain
2. Pericardial rubs
3. Electrocardiogram (ECG)
4. Pericardial effusion
5. C-reactive protein (CRP)

Limitations



1. Approvals will be granted for 12 months.
2. For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

References

1. Arcalyst [package insert]. London, UK: Kiniksa Pharmaceuticals (UK), Ltd.; May 2021.
2. Hoffman HM, Throne ML, Amar NJ, et al. Efficacy and safety of riloncept (interleukin-1 trap) in patients with cryopyrin-associated periodic syndromes. Results from two sequential placebo-controlled studies. *Arthritis Rheum.* 2008;58(8):2443-52.
3. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 15, 2022 from: <https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm>.
4. Adler Y, Charron P, Imazio M, et al. 2015 ESC Guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC) Endorsed by: The European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J.* 2015 Nov 7;36(42):2921-64.
5. Chiabrando JG, Bonaventura A, Vecchié, et al. Management of acute and recurrent pericarditis: JACC State-of-the-art review. *J Am Coll Cardiol.* 2020;75(1):76-92.
6. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap riloncept in recurrent pericarditis. *N Engl J Med.* 2021;384(1):31-41.
7. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al; Canakinumab in CAPS Study Group. Use of canakinumab in the cryopyrin-associated periodic syndrome. *N Engl J Med.* 2009;360(23):2416-2425.
8. Garg M, de Jesus A, Chapelle D, et al. Riloncept maintains long-term inflammatory remission in patients with deficiency of the IL-1 receptor antagonist. *JCI Insight.* 2017;2(16):e94838. <https://doi.org/10.1172/jci.insight.94838>.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

