

Arcalyst (rilonacept)
Effective 07/01/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Arcalyst®(rilonacept) is an interleukin-1 β (IL-1 β) blocker that is indicated for Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and for treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Cryopyrin-Associated Periodic Syndromes, including: Familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)

ALL of the following:

1. Diagnosis of one of the following:
 - a. Familial cold autoinflammatory syndrome (FCAS)
 - b. Muckle-Wells syndrome (MWS)
2. Member is \geq 12 years of age
3. **ONE** of the following:
 - a. Evidence of symptoms indicative of the disease (see appendix for examples)

- b. Confirmation of diagnosis through genetic testing
- 4. Appropriate dosing

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

ALL of the following:

- 1. Diagnosis of deficiency of interleukin-1 receptor antagonist
- 2. Confirmation of diagnosis through genetic testing
- 3. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to Kineret® (anakinra)
- 4. Appropriate dosing

Recurrent pericarditis

ALL of the following:

- 1. Diagnosis of recurrent pericarditis
- 2. Member is ≥ 12 years of age
- 3. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to BOTH of the following:
 - a. aspirin
 - b. Nonsteroidal anti-inflammatory drugs (NSAID)
- 4. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or a contraindication to ALL corticosteroids
- 5. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to BOTH of the following:
 - a. Colchicine
 - b. Kineret® (anakinra)
- 6. Appropriate dosing

Continuation of Therapy

Reauthorization by prescriber will infer a positive response to therapy and dosing is appropriate.

Limitations

- 1. Initial approvals will be granted for 6 months
- 2. Reauthorizations will be granted for 12 months
- 3. Dosing information:

	Pediatric Dosing	Adult Dosing
Arcalyst® (riloncept) Single-use vial: 220 mg of lyophilized powder for reconstitution/20 mL QTY 1 vial=220 mg	CAPS (includes FCAS, MWD) (12 to 17 years of age): SQ: Loading: 4.4 mg/kg (maximum: 320 mg) Maintenance: 2.2 mg/kg (maximum: 160 mg) weekly DIRA (weight ≥10 kg): 4.4 mg/kg SQ (maximum: 320 mg) weekly (one or two injections)	CAPS (includes FCAS, MWD): Members ≥18 years of age: Loading: 320 mg delivered as two, 2 mL, SQ injections of 160 mg on the same day at different sites Maintenance: 160 mg, delivered as one, 2 mL, SQ injection weekly DIRA: Members ≥18 years of age: 320 mg SQ (two injections on the same day at different sites) weekly



	Recurrent pericarditis (12 to 17 years of age): SQ: Loading: 4.4 mg/kg SQ (maximum: 320 mg) Maintenance: 2.2 mg/kg SQ (maximum: 160 mg) once weekly	Recurrent pericarditis: Members ≥18 years of age: Loading: 320 mg delivered as two 160 mg SQ injections Maintenance: 160 mg SQ once weekly
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Appendix

Disease Symptoms

Tumor necrosis factor receptor associated periodic syndrome (TRAPS): characterized by recurrent fevers over months or years every five to six weeks, focal myalgias, conjunctivitis, periorbital edema, abdominal pain, monoarticular arthritis, and rash.

Recurrent pericarditis: The predominant feature of recurrent pericarditis is usually pleuritic chest pain (often sharp, worse when lying flat, and alleviated when leaning forward), which may follow exertion. Some members may also report dyspnea or malaise.

Familial cold autoinflammatory syndrome (FCAS): mildest phenotype; characterized by intermittent cold-induced rash with fever and arthralgia.

Muckle-Wells syndrome (MWS): characterized by recurrent episodes of fever and urticaria associated with joint and ocular manifestations, deafness and reactive amyloid A amyloidosis.

Neonatal onset multisystem inflammatory disease (NOMID): most severe spectrum of the disease; characterized by erythematous rash resembling urticaria, fever, impaired growth, chronic meningitis, hearing loss, uveitis, lymphadenopathy and hepatosplenomegaly. Limb and joint pain is common.

Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD): characterized by episodic attacks of fever lasting three to seven days are accompanied, in most cases, by chills, cervical lymphadenopathy, abdominal pain, vomiting, and/or diarrhea. Other symptoms include headache, arthralgias/arthritis, aphthous ulceration, a pleomorphic rash, and splenomegaly. Elevated levels of immunoglobulin D (IgD) are often present.

References

1. Arcalyst® [package insert]. Tarrytown (NY): Regeneron Pharmaceuticals, Inc; 2021 May

Review History

06/14/2023 - Created for P&T in order to match MH UPPL. Effective 7/1/23.

