



Arcalyst® (riloncept)

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Definition

Arcalyst is a targeted inhibitor of interleukin-1 (IL-1), the key driver of inflammation in cryopyrin-associated periodic syndromes (CAPS). Riloncept acts as a decoy receptor that binds IL-1 beta and the blocks IL-1 beta signaling, thereby preventing its interaction with cell surface receptors. It also binds IL-1 alpha and IL-1 receptor antagonist with reduced affinity

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

I. INITIAL APPROVAL CRITERIA

*Arcalyst may be considered medically necessary if the below condition is met **AND** use is consistent with the medical necessity criteria that follows:*

1. Cryopyrin-Associated Periodic Syndromes

- a. Diagnosis of FCAS or MWS;
- b. Prescribed by or in consultation with a rheumatologist;
- c. Age \geq 12 years;
- d. Dose does not exceed a loading dose of 320 mg (as two injections) and once weekly dosing of 160 mg (as a single injection)

II. RENEWAL CRITERIA

- Patient continues to meet INITIAL APPROVAL CRITERIA.
- Member is responding positively to therapy.

Dosage/Administration

Indication	Dose
CAPS (FCAS, MWS)	<ul style="list-style-type: none">– Age ≥ 18 years; 320 mg SC loading dose followed by 160 mg SC once weekly.– Age 12 to 17 years: 4.4 mg/kg SC loading dose followed by 2.2 mg/kg SC once weekly.

Applicable Procedure Codes

J2793	Injection, rilonacept, 1 mg, 1 billable unit = 1 mg
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Applicable NDCs

61755-0001-xx	Arcalyst single use vial; 220 mg (each reconstituted vial delivers 160 mg)
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Applicable Diagnosis Codes

ICD-10	ICD-10 Description
L50.2	Urticaria due to cold and heat [familial cold autoinflammatory syndrome (FCAS)]

References

1. Product Information: ARCALYST(R) subcutaneous injection, rilonacept subcutaneous injection. Regeneron Pharmaceuticals, Inc. (per Manufacturer), Tarrytown, NY, 2014.
2. Hoffman HM, Rosengren S, Boyle DL, et al. Prevention of cold-associated acute inflammation in familial cold autoinflammatory syndrome by interleukin-1 receptor antagonist. *Lancet*. 2004;364(9447):1779-1785.
3. Shinkai K, McCalmont TH, Leslie KS. Cryopyrin-associated periodic syndromes and autoinflammation. *Clin Exp Dermatol*. 2008;33(1):1-9.