

Arcalyst® (rilonacept)



When requesting Arcalyst® (rilonacept), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Arcalyst is an interleukin-1 blocker indicated for the treatment of Cryopyrin Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

Approved Off-Label Compendial Use(s)

None

Coverage Guidelines

The individual must meet **all** of the following criteria for approval:

- Does not have active or chronic infection
- Arcalyst (rilonacept) will not be given in combination with tumor necrosis factor (TNF) – inhibitor (e.g., adalimumab, etanercept, golimumab, infliximab)
- Is at least 12 years of age
- Must have either one of the following Cryopyrin Associated Periodic Syndromes CAPS subtype: Familial Cold Auto-inflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)

Approval duration (initial and renewal): 12 months

Dosing Recommendations

For adult patients 18 years and older:

The recommended dose is a loading dose of 320 mg administered via subcutaneous injection followed by 160 mg once weekly.

For pediatric patients aged 12 to 17 years:

The recommended dose is a loading dose of 4.4 mg/kg, up to a maximum of 320 mg administered via subcutaneous injection followed by 2.2 mg/kg, up to a maximum of 160 mg once weekly.

References

1. Arcalyst prescribing information. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. September 2016.
2. Yu JR, Leslie KS. Cryopyrin-Associated Periodic Syndrome: An Update on Diagnosis and Treatment Response. *Curr Allergy Asthma Rep.* 2011(11):12-20.
3. American College of Rheumatology. Cryopyrin-Associated Autoinflammatory Syndromes. Available at: <https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Cryopyrin-Associated-Autoinflammatory-Syndrome-CAPS-Juvenile>.