

## 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 autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS), in adults and children 12 years of age and older.

### Coverage Guidelines

#### Cryopyrin-Associated Periodic Syndromes (CAPS)

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

- Is 12 years of age or older; AND
- Arcalyst is prescribed by or in consultation with a rheumatologist, geneticist, allergist, immunologist, or dermatologist.

For re-authorization, the individual must be responding to Arcalyst therapy.

**Approval duration (initial): 3 months**

**Approval duration (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, administered via subcutaneous injection once weekly.

### References

1. Arcalyst® for injection [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; September 2016.
2. Shinkai K, McCalmont TH, Leslie KS. Cryopyrin-associated periodic syndromes and autoinflammation. *Clin Exp Dermatol*. 2008;33:1-9.
3. Ozen S, Hoffman HM, Frenkel J, et al. Familial Mediterranean Fever (FMF) and beyond: a new horizon. Fourth International Congress on the Systemic Autoinflammatory Diseases held in Bethesda, USA, 6-10 November 2005. *Ann Rheum Dis*. 2006;65:961-964.
4. Rilonacept (Arcalyst®). In: DRUGDEX® System Micromedex. Greenwood Village, CO: Thompson Reuters (Healthcare) Inc. [Updated; November 6, 2019; Accessed April 21, 2020].