

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** Arcalyst

**Drug(s):** Arcalyst (rilonacept)

**Covered Uses:**

Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS).

**Required Medical Information:**

- Genetic test report;
- Skin biopsy if performed;
- Serum amyloid;
- C-reactive protein;
- Documentation of symptoms affecting activities of daily living (ADLs).

**Age Restrictions:**

Must be 12 years of age or older.

**Prescriber Restrictions:**

Rheumatologist or immunologist

**Other Criteria:**

Rilonacept may be considered medically necessary when all of the following are met:

- Genetic test identifying CIAS1 (Cold-Induced Autoinflammatory Syndrome 1) gene mutation (also known as NLRP3, NALP3 or PYPAF);
- Impairment of ADLs due to CAPS symptoms.

Extension of therapy will be medically necessary if documentation identifies symptom improvement or disease stability.

**Exclusion Criteria:**

- Dosing other than FDA approved dosing regimen;
- In combination with other interleukin-1 inhibitor;
- In combination with TNF inhibitor;

**Coverage Duration:**

Initial 6 month approval followed by an additional 6 months if medically necessary.