

Reference number
1800-A

## SPECIALTY GUIDELINE MANAGEMENT

### ARCALYST (rilonacept)

#### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

Treatment of Cryopyrin Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years of age and older.

##### B. Compendial Uses

Prevention of gout flares in patients initiating or continuing urate-lowering therapy

All other indications are considered experimental/investigational and are not a covered benefit.

#### II. CRITERIA FOR INITIAL APPROVAL

##### A. **Cryopyrin-Associated Periodic Syndrome (CAPS)**

Authorization of 24 months may be granted for treatment of CAPS, including FCAS and MWS.

##### B. **Prevention of Gout Flares in Members Initiating or Continuing Urate-Lowering Therapy**

Authorization of 4 months may be granted when ALL of the following criteria are met:

1. Member had two or more gout flares within the previous 12 months
2. Member had an inadequate response, intolerance or contraindication to maximum tolerated doses of non-steroidal anti-inflammatory drugs and colchicine
3. Member will receive Arcalyst concurrently with urate-lowering therapy (i.e., allopurinol or febuxostat)

#### III. CONTINUATION OF THERAPY

##### A. **Cryopyrin-Associated Periodic Syndrome (CAPS)**

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

##### B. **Prevention of Gout Flares in Members Initiating or Continuing Urate-Lowering Therapy**

Authorization of 4 months may be granted to members who meet ALL of the following criteria:

1. Member has achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days) compared to baseline
2. Member will receive Arcalyst concurrently with urate-lowering therapy (i.e., allopurinol or febuxostat)

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#### IV. REFERENCES

1. Arcalyst [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2016.
2. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics. Available with subscription. URL: [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Accessed January 01, 2018.
3. Mitha E, Schumacher HR, Fouche L, et al. Rilonacept for gout flare prevention during initiation of uric acid-lowering therapy: results from the PRESURGE-2 international, phase 3, randomized, placebo-controlled trial. *Rheumatology (Oxford)*. 2013; 52(7):1285-1292. URL: <http://rheumatology.oxfordjournals.org/content/52/7/1285.long>.
4. Schumacher HR Jr, Evans RR, Saag KG, et al: Rilonacept (interleukin-1 trap) for prevention of gout flares during initiation of uric acid-lowering therapy: results from a phase III randomized, double-blind, placebo-controlled, confirmatory efficacy study. *Arthritis Care Res (Hoboken)*. 2012; 64(10):1462-1470.
5. Clinical Consult. CVS/caremark Clinical Programs Review. Focus on Rheumatology Clinical Programs. July 2015.