| 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 for the prevention of gout flares when initiating or continuing urate-lowering therapy 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)

| Reference number |
| --- |
| 1800-A |

## 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. Accessed January 24, 2019.
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.