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 when ALL of the following criteria are met:
1. Member has a diagnosis of CAPS, including FCAS and MWS.
2. Member is 12 years of age or older.

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 is 18 years of age or older
2. Member's serum uric acid concentration is greater than or equal to 445 µmol/L (7.5 mg/dL) prior to initiating Arcalyst
3. Member had two or more gout flares within the previous 12 months
4. Member had an inadequate response, intolerance or contraindication to maximum tolerated doses of non-steroidal anti-inflammatory drugs and colchicine
5. 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 is 18 years of age or older
2. Member has achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days compared to baseline)
3. Member has continued to receive urate-lowering therapy concurrently with Arcalyst.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Arcalyst [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2014.
2. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics. Available with subscription. URL: www.micromedexsolutions.com. Accessed July 10, 2016.
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.