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)
IV. REFERENCES