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.

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.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Cryopyrin-associated periodic syndrome (CAPS)
Authorization of 12 months may be granted for treatment of CAPS when all of the following criteria are met:
A. Member has a diagnosis of familial cold auto-inflammatory syndrome (FCAS) with classic signs and symptoms (i.e., recurrent, intermittent fever and rash that were often exacerbated by exposure to generalized cool ambient temperature) or Muckle-Wells syndrome (MWS) with classic signs and symptoms (i.e., chronic fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature).
B. Member has functional impairment limiting the activities of daily living.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are using Arcalyst for an indication outlined in Section II and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. OTHER

A. Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs (e.g., Olumiant, Rinvoq, Xeljanz), and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer rilonacept to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of treatment.

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

B. The requested drug will not be used concomitantly with any other biologic DMARD (e.g., adalimumab, anakinra, canakinumab, etanercept, infliximab, tocilizumab) or targeted synthetic DMARD (e.g. tofacitinib).

V. REFERENCES

1. Arcalyst [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2016.
2. Centers for Disease Control and Prevention. Tuberculosis (TB). TB risk factors. Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Accessed: August 15, 2019.