PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Interleukin-1 Blockers for Cryopyrin-Associated Periodic Syndromes Preferred Specialty Management Policy

- Arcalyst® (rilonacept injection – Regeneron Pharmaceuticals)
- Ilaris® (canakinumab subcutaneous injection – Novartis)

REVIEW DATE: 11/18/2020

OVERVIEW

Arcalyst and Ilaris are interleukin-1 (IL-1) blockers indicated for the treatment of **cryopyrin-associated periodic syndromes**, including familial cold autoinflammatory syndrome and Muckle-Wells Syndrome.[1-2] Arcalyst is indicated in patients ≥ 12 years of age, whereas Ilaris is approved in those ≥ 4 years of age. Of note, Ilaris is also indicated in other conditions, including systemic juvenile idiopathic arthritis in patients ≥ 2 years of age; tumor necrosis factor receptor associated periodic syndrome, in adult and pediatric patients; hyperimmunoglobulin D Syndrome/mevalonate kinase deficiency, in adult and pediatric patients; and familial Mediterranean fever, in adult and pediatric patients. However, these indications are not targeted in this policy.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For both medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Prior Authorization Policy* criteria, but has not tried a Preferred Product, a review will be offered for the Preferred Product using the respective standard *Prior Authorization Policy* criteria. All approvals are for the duration noted below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation: Documentation of previous therapy will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts.

Automation: None.

Preferred Product: Ilaris
Non-Preferred Product: Arcalyst

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Arcalyst	**1. Cryopyrin-Associated Periodic Syndromes, Initial Therapy.** Note: This includes Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease or chronic infantile neurological cutaneous and articular syndrome. **A)** Approve for 3 months if the patient meets BOTH of the following (i and ii): **i.** The patient meets the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria; AND **ii.** The patient has tried Ilaris **[documentation required]**. **B)** If the patient has met criterion 1Ai (the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria) but criterion 1Aii is not met, offer to review for Ilaris using the standard *Inflammatory Conditions – Ilaris Prior Authorization Policy* criteria. **2. Cryopyrin-Associated Periodic Syndromes, Patient is Currently Taking Arcalyst.** **A)** Approve Arcalyst for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has been established on Arcalyst for ≥ 90 days; OR **b)** The patient has tried Ilaris **[documentation required]**. **B)** If the patient has met criterion 2Ai (the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria), but criterion 2Aii is not met, offer to review for Ilaris using the standard *Inflammatory Conditions – Ilaris Prior Authorization Policy* criteria. **3. Other Conditions.** Approve Arcalyst if the patient meets the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria.

REFERENCES

1. Arcalyst for injection [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; September 2016.
2. Ilaris for subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2016.