PREFERRED SPECIALTY MANAGEMENT POLICY

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

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

REVIEW DATE: 12/21/2022

OVERVIEW

Arcalyst and Ilaris are interleukin-1 (IL-1) blockers indicated for the treatment of **cryopyrin-associated periodic syndromes (CAPS)**, 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.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product for CAPS. 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. <u>Cryopyrin-Associated Periodic Syndromes, Initial Therapy</u>.** <u>Note</u>: 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 6 months if the patient meets BOTH of the following (i <u>and</u> ii): **i.** Patient meets the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria; AND **ii.** 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. <u>Cryopyrin-Associated Periodic Syndromes, Patient is Currently Taking Arcalyst</u>.** **A)** Approve <u>Arcalyst</u> for 1 year if the patient meets BOTH of the following conditions (i <u>and</u> ii): **i.** Patient meets the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following conditions (a <u>or</u> b): **a)** Patient has been established on Arcalyst for ≥ 90 days; OR **b)** 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. <u>Other Conditions</u>.** Approve Arcalyst if the patient meets the standard *Inflammatory Conditions – Arcalyst Prior Authorization Policy* criteria.

REFERENCES

1. Arcalyst® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron; March 2021.
2. Ilaris® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; September 2020.