



BlueCross BlueShield
of Alabama

Arcalyst®/Ilaris®
Prior Authorization Coverage Criteria

DRUG CLASS: Biologic Response Modifiers – AHFS 92:00
POLICY #: 0197
CATEGORY: Commercial

Brand Name	Generic Name	Dosage Form
Arcalyst®	rilonacept	Injection, subcutaneous
Ilaris®	canakinumab	Injection, subcutaneous

PROGRAM RATIONALE:

- The intent of the Arcalyst/Ilaris prior authorization (PA) program is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical guidelines. The PA defines appropriate use as the FDA approved indication of the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children (12 years of age and older for Arcalyst; 4 years and older for Ilaris. The PA process discourages use of these agents as a substitute for Kineret (anakinra) in the treatment of rheumatoid arthritis (RA) or for off-label uses and also assures the patient is not being treated concurrently with another IL-1 blocker or a tumor necrosis factor (TNF) antagonist.

BENEFIT DESIGN:

Prior Authorization:

Claims for Arcalyst and Ilaris will reject with the message that prior authorization is required.

COVERAGE CRITERIA:

A) Prior Authorization:

Coverage is provided if **all** of the following bullets apply:

- The patient is 12 years of age and older for Arcalyst or 4 years of age and older for Ilaris
AND
- The patient has been diagnosed with CAPS, including FCAS and MWS
AND
- The patient does not have an active or chronic infection (e.g., tuberculosis, HIV, hepatitis B)
AND
- If the patient has been previously treated with another IL-1 inhibitor (Kineret [anakinra]) or a TNF-α blocking agent (Enbrel [etanercept], Remicade [infliximab], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab]) the agent will be discontinued before initiating Arcalyst or Ilaris.

* If prior authorization is approved, coverage may be given for up to 12 months.

FDA APPROVED INDICATIONS AND DOSAGE:

Available Products	Indication	Route of Administration	Dosage and Administration
Arcalyst (rilonacept)	Treatment of CAPS including FCAS and MWS in adults and children 12 years of age and older	Subcutaneous injection	320mg subcutaneously on day 0 then 160mg once weekly
Ilaris (canakinumab)	Treatment of CAPS including FCAS and MWS in adults and children 4 years of age and older	Subcutaneous injection	150mg subcutaneously every 8 weeks

CAPS - Cryopyrin-Associated Periodic Syndromes
FCAS – Familial Cold Auto-Inflammatory Syndrome
MWS – Muckle-Wells Syndrome

REFERENCES:

1. Arcalyst® [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2010.
2. Shinkai K, McCalmont TH, Leslie KS. Cryopyrin-associated periodic syndromes and autoinflammation. *Clin Exp Dermatol*. 2007;33:1-9.
3. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2009.
4. Micromedex Healthcare Series Web site. Available at: <http://www.thomsonhc.com.ezproxy.samford.edu/home/dispatch> Accessed June 25, 2009.
5. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. *N Engl J Med* 360;23:2416-25.

POLICY HISTORY:

- Pharmacy Review Date: July 16, 2008
- Date of Pharmacy & Therapeutics Committee Approval: November 12, 2008
- Original Effective Date: December 18, 2008
- Pharmacy Review Date: September 18, 2009
- Date of Pharmacy & Therapeutics Committee Approval: November 3, 2009
- Pharmacy Review Date: October 13, 2010
- Date of Pharmacy & Therapeutics Committee Approval: November 17, 2010
- Pharmacy Review Date: April 6, 2011
- Date of Pharmacy & Therapeutics Committee Approval: May 4, 2011
- Effective Date of Revisions: July 1, 2011
- Pharmacy Review Date: October 19, 2011
- Date of Pharmacy & Therapeutics Committee Approval: November 2, 2011
- Effective Date of Revisions: January 1, 2012
- Next Review Date: November 2012

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely

responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.