PRIOR AUTHORIZATION CRITERIA FOR USE OF INTERLEUKIN-1 BETA BLOCKERS

{ ARCALYST (rilonacept) and ILARIS (canakinumab)}

Arca\-lyst is a dimeric fusion protein that blocks the activity of interleukin-1 (IL-1). It is indicated to treat cryopyrin-associated periodic syndromes (CAPS), a group of rare inflammatory diseases.

Ilaris is a human monoclonal anti-IL-1 beta antibody of the immunoglobulin G1 (IgG1)/kappa isotype. It is indicated to treat cryopyrin-associated periodic syndromes (CAPS), a group of rare inflammatory diseases as well as in the treatment of systemic juvenile idiopathic arthritis (SJIA) in children 2 years of age and older.

The following criteria must be met for approval of Arca\-lyst (rilonacept) or Ilaris (canakinumab) in the treatment of Cryopyrin-Associated Periodic Syndrome (CAPS):

- Submitted laboratory documentation of a genetic mutation in the Cold-Induced Autoinflammatory Syndrome 1 (CIAS1—sometimes referred to as the NLRP3)
- Office notes documenting a diagnosis of Muckle-Wells Syndrome (MWS) in patients 12 years of age or older (chronic fever and rash; sometimes exacerbated by generalized cold exposure. MWS may be accompanied with deafness or amyloidosis.

OR

- Office notes documenting a diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS) in patients 12 years of age or older (recurrent intermittent episodes of rash and fever that primarily followed natural, artificial or both types of generalized cold exposure).

AND

- Dosing must correspond to above noted FDA dosing; only once weekly dosing will be covered for Arca\-lyst, every other month dosing for Ilaris.
Neither Arcalyst nor Ilaris is FDA approved for the treatment of neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA). Neither medication will be approved for these indications. Arcalyst (rilonacept) and Ilaris (canakinumab) are interleukin-1 (IL-1) blockers indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children. There is currently no reliable evidence that Arcalyst or Ilaris are efficacious in patients who do not exhibit the NLRP3 (CIAS1) generic mutation. Neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA) are classified as under CAPS, however, the use of Arcalyst/Ilaris is not recommended in these latter syndromes. These autoinflammatory syndromes are caused by episodes of inflammation and are distinct from autoimmune disorders.

Ilaris is also indicated for the treatment of Active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

The following criteria, documented with submitted medical records as well as prescription claims history must be met for prior authorization of Ilaris in the treatment of systemic juvenile idiopathic arthritis:

- Diagnosis of systemic juvenile idiopathic arthritis with disease activity greater than 6 months documented by a rheumatologist

AND

- Treatment with at least one oral systemic agent for systemic juvenile idiopathic arthritis was ineffective or not tolerated (examples are glucocorticoids and/or methotrexate).

Dosing of Arcalyst in the treatment of Cryopyrin-Associated Periodic Syndrome (CAPS) is as follows:

Arcalyst is available in 220 mg, single-use vials.

- Children, ages 12-17---Treatment should be initiated with a loading dose of 4.4 mg/kg, up to a maximum of 320 mg, delivered as 1 or 2 subcutaneous injections, with a maximum single-injection volume of 2 mL. Dosing should be continued with a once-weekly injection of 2.2 mg/kg, up to a maximum of 160 mg, administered as a single subcutaneous injection, up to 2 mL. If the initial dose is given as 2 injections, they should be given on the same day at 2 different sites. Rilonacept should not be given more often than once weekly.

- Adults, 18 years of age and older--Treatment should be initiated with a loading dose of 320 mg delivered as two, 2 mL, subcutaneous injections of 160 mg each given on the same day at 2 different sites. Dosing should be continued with a once-weekly injection of 160 mg administered as a single, 2 mL, subcutaneous injection. Rilonacept should not be given more often than once weekly.

Injection is for subcutaneous use only. Sites for injection, abdomen, thigh, or upper arm, should be rotated. Injections should never be made at sites that are bruised, red, tender, or hard.
Dosing of Ilaris (canakinumab) in the treatment of Cryopyrin-Associated Periodic Syndrome (CAPS) is as follows:

- Adults and children 4 years of age and older, body weight greater than 40 kg: 150 mg subcutaneously every 8 weeks. For those children with a body weight between 15 and 40 kg, 2 mg/kg subcutaneously every 8 weeks.

Dosing of Ilaris (canakinumab) in the treatment of Active Systemic Juvenile Idiopathic Arthritis is as follows:

- In children 2 years of age and older for SJIA patients with a body weight greater than or equal to 7.5 kg, a dose of 4 mg/kg (with a maximum of 300 mg) is administered every four weeks via subcutaneous injection.

Both of these medications must be obtained through specialty pharmacies after approval is obtained.