Rationale for Inclusion in PA Program

Background
Arcalyst is used in the treatment of two Cryopyrin-Associated Periodic Syndromes (CAPS) disorders: Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). Arcalyst blocks interleukin-1 which is a signaling protein secreted by certain immune-related cells in the body. Interleukin-1 acts as a messenger to regulate inflammatory responses, but in excess it can be harmful and has been shown to be key in the inflammation seen in CAPS sufferers with Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) (1).

Regulatory Status
FDA-approved indication: Arcalyst (rilonacept) is an interleukin-1 blocker indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older (1).

Interleukin-1 blockade may interfere with immune response to infections. Serious, life threatening infections have been reported in patients taking Arcalyst. In addition, taking Arcalyst with Tumor Necrosis Factor inhibitors or other interleukin-1 blockers may further increase the risk of serious infections and an increased risk of neutropenia. The concomitant administration of Arcalyst with TNF-blocking agents is not recommended. Discontinue treatment with Arcalyst if a patient develops a serious infection. Arcalyst should not be initiated in patients with active or chronic infections (1).

Live vaccines should not be given concurrently with Arcalyst. Prior to initiation of therapy with Arcalyst, patients should receive all recommended vaccinations (1).

Summary
Arcalyst (rilonacept) is an interleukin-1 blocker indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. The concomitant administration of Arcalyst with TNF-blocking agents or other interleukin-1 blockers
ARCALYST
(rilonacept)

is not recommended due to the increased risk of serious infection or neutropenia. Arcalyt should not be initiated in patients with active or chronic infections. Live vaccines should not be given concurrently with Arcalyt. Lifetime treatment is required to maintain the patient in remission (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Arcalyt while maintaining optimal therapeutic outcomes.

References