



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Arcalyst (rilonacept) is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS); for maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); and for recurrent pericarditis (RP). 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, DIRA and pericarditis (1).

Regulatory Status

FDA-approved indications: Arcalyst (rilonacept) is an interleukin-1 blocker indicated for: (1)

1. 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
2. Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more
3. Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older

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 (TNF) 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 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).

The safety and effectiveness of Arcalyst in CAPS/FCAS/MWS and recurrent pericarditis in patients less than 12 years of age and in DIRA pediatric patients weighing less than 10 kg have

ARCALYST (rilonacept)

not been established (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; for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); and for recurrent pericarditis (RP). The concomitant administration of Arcalyst with TNF-blocking agents or other interleukin-1 blockers is not recommended due to the increased risk of serious infection or neutropenia. Arcalyst should not be initiated in patients with active or chronic infections. Live vaccines should not be given concurrently with Arcalyst. 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 Arcalyst while maintaining optimal therapeutic outcomes.

References

1. Arcalyst [package insert]. London, UK: Kiniksa Pharmaceuticals, Ltd.; May 2021.