BlueCross BlueShield Federal Employee Program

KINERET
(anakinra)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Kineret is in a class of medications called interleukin-1 (IL-1) receptor antagonists. This means that Kineret works by blocking the activity of interleukin, a protein in the body that can induce inflammatory and immunological responses. Interleukin-1 (IL-1) is produced by the body as part of an inflammatory reaction in diseases such as Rheumatoid Arthritis (RA), Cryopyrin-Associated Periodic Syndromes (CAPS)- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) and Deficiency of Interleukin-1 Receptor Antagonist (DIRA). Excess IL-1 can lead to pain, swelling, stiffness of the joints, and systemic inflammation with skin and bone involvement. Kineret can help manage the excess levels of IL-1 in the body by blocking its activity (1).

Regulatory Status

FDA-approved indications: Kineret is an interleukin-1 receptor antagonist indicated for: (1)

Rheumatoid Arthritis (RA) - Reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs).

Cryopyrin-Associated Periodic Syndromes (CAPS) - Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

Deficiency of Interleukin-1 Receptor Antagonist (DIRA) – Treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

Off-Label Uses: (2-6)

Kineret is also used off label for the following indications:

- Systemic juvenile idiopathic arthritis (sJIA)
- Adult-onset Still's disease
- Gout and pseudogout (calcium pyrophosphate deposition)
- CAR T-Cell Related Toxicities

Treatment should not be initiated in patients with an active infection and Kineret should be discontinued in patients with RA if a serious infection develops. Patients with NOMID should be

assessed for the risk of a flare if Kineret therapy is discontinued against continuing treatment when an infection occurs. Concurrent use with tumor necrosis factor (TNF) blocking agents is not recommended. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported. Live vaccines should not be given concurrently with Kineret and neutrophil counts should be assessed prior to initiation of and during therapy (1).

Safety and efficacy of Kineret in pediatric patients for uses other than neonatal-onset multisystem inflammatory disease (NOMID) and deficiency of interleukin-1 receptor antagonist (DIRA) have not been established. Kineret is not recommended for pediatric use in juvenile rheumatoid arthritis (1).

Summary

Kineret is FDA-approved for the treatment of patients with Cryopyrin-Associated Periodic Syndrome (CAPS) - Neonatal-Onset Multisystem Inflammatory Disease (NOMID) and Deficiency of Interleukin-1 Receptor Antagonist (DIRA), and adult patients for the treatment of moderate to severely active rheumatoid arthritis (RA) who have had inadequate response or intolerance to conventional therapy. Kineret is also used off-label for systemic juvenile idiopathic arthritis (sJIA), adult-onset Still's disease, gout and pseudogout, and CAR T-Cell Related Toxicities. Kineret carries warnings due to increased risk of serious infections due to immunosuppression and hypersensitivity reactions (1-6).

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

References

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3. Efthimiou P, Paik P K, Bielory L. Diagnosis and Management of Adult Onset Still's Disease. *Ann Rheum Dis*. 2006 May;65(5):564-72. Epub 2005 Oct 11.
4. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis*. 2017;76:29–42.
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