



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Kevzara (sarilumab) is subcutaneous injectable treatment form that helps regulate inflammation by binding to a protein (interleukin IL-6) which is involved in inflammatory signaling. Kevzara binds to IL-6, prevents it from binding to its receptor, and inhibits its ability to trigger the inflammatory response (1).

Regulatory Status

FDA-approved indications: Kevzara is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of (1):

- adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
- adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.
- patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA).

Evaluate patients for tuberculosis infection prior to initiating treatment with Kevzara. Do not administer Kevzara to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering Kevzara. Consider anti-tuberculosis therapy prior to initiation of Kevzara in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Kevzara should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1).

Kevzara affects the immune system, thus patients may have a greater risk of getting an infection. Serious allergic reactions have been reported with the use of Kevzara. Caution should be exercised when considering the use of Kevzara in patients with a chronic infection or history of recurrent infection, and in patients with active Crohn's Disease (1).

Patients treated with Kevzara should not receive live vaccines (1).

Safety and effectiveness of Kevzara in pediatric patients below the age of 18 with RA or PMR have



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KEVZARA (sarilumab)

not been established. Safety and effectiveness of Kevzara in pediatric patients below the age of 2 with pJIA have not been established (1).

Summary

Kevzara is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis, polymyalgia rheumatica, and polyarticular juvenile idiopathic arthritis. Kevzara interacts with IL-6 to regulate inflammation signaling. It is administered as an injection under the skin. It should not be used in combination with other biological DMARDs or targeted synthetic DMARDs. Kevzara may inhibit the immune system and patients should be monitored for infections, including tuberculosis and should not receive live vaccines while on treatment. Safety and effectiveness of Kevzara in pediatric patients below the age of 18 with RA or PMR have not been established. Safety and effectiveness of Kevzara in pediatric patients below the age of 2 with pJIA have not been established (1).

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

References

1. Kevzara [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; September 2024.