BlueCross BlueShield Federal Employee Program

SKYRIZI (risankizumab-rzaa)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Skyrizi (risankizumab-rzaa) is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Skyrizi inhibits the release of pro-inflammatory cytokines and chemokines (1).

Regulatory Status

FDA-approved indications: Skyrizi is an interleukin-23 antagonist indicated for the treatment of: (1)

- moderate-to-severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy.
- active psoriatic arthritis (PsA) in adults.
- moderately to severely active Crohn's disease (CD) in adults.
- moderately to severely active ulcerative colitis (UC) in adults.

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

Skyrizi affects the immune system, thus patients may be at greater risk for infection. If a patient develops a serious infection or is not responding to standard therapy for the infection, monitor the patient closely and discontinue Skyrizi therapy until the infection resolves (1).

For the treatment of Crohn's disease, there is a risk for hepatotoxicity. For the treatment of CD and UC, liver enzymes and bilirubin should be evaluated at baseline and during induction at least up to 12 weeks of treatment. They should be monitored thereafter according to routine patient management (1).

Avoid use of live vaccines in patients treated with Skyrizi. There is no data available on the response to live or inactive vaccines (1).

The safety and effectiveness of Skyrizi in pediatric patients less than 18 years old have not been established (1).

Summary

Skyrizi (risankizumab-rzaa) is an interleukin-23 antagonist indicated for the treatment of plaque psoriasis or psoriatic arthritis. Skyrizi affects the immune system, thus patients may be at greater risk for infection. Patients should be monitored closely for signs and symptoms of infection during treatment and evaluated for tuberculosis (TB) infection prior to initiating treatment with Skyrizi. The safety and effectiveness of Skyrizi in pediatric patients less than 18 years old have not been established (1).

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

References

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.