

ENSPRYNG (satralizumab-mwge)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Enspryng (satralizumab-mwge) is an interleukin-6 (IL-6) receptor antagonist. The precise mechanism by which Enspryng exerts therapeutic effects in neuromyelitis optica spectrum disorder (NMOSD) is unknown but is presumed to involve inhibition of IL-6-mediated signaling through binding to soluble and membrane-bound IL-6 receptors (1).

Regulatory Status

FDA-approved indication: Enspryng is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive (1).

Enspryng is contraindicated in patients with active hepatitis B infection or active or untreated latent tuberculosis. Prior to initiating Enspryng, patients should be screened for Hepatitis B virus (HBV) and patients should be evaluated for active tuberculosis and tested for latent infection (1).

Live or live-attenuated vaccines should not be given concurrently with Enspryng because clinical safety has not been established. Live or live-attenuated immunizations should be administered at least 4 weeks prior to initiation of Enspryng and, whenever possible, at least 2 weeks prior to initiation of Enspryng for non-live vaccines (1).

Mild and moderate elevations of liver enzymes have been observed in patients treated with Enspryng. Liver transaminases and serum bilirubin should be assessed prior to initiation of treatment with Enspryng. ALT and AST levels should be monitored every 4 weeks for the first 3 months of treatment, followed by every 3 months for one year, and thereafter, as clinically indicated (1).

Decreases in neutrophil counts were also observed in patients treated with Enspryng. Neutrophil counts should be monitored 4 to 8 weeks after initiation of therapy, and thereafter at regular clinically determined intervals (1).

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



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Summary

Enspryng (satralizumab-mwge) is an interleukin-6 (IL-6) receptor antagonist. The precise mechanism by which Enspryng exerts therapeutic effects in neuromyelitis optica spectrum disorder (NMOSD) is unknown but is presumed to involve inhibition of IL-6-mediated signaling through binding to soluble and membrane-bound IL-6 receptors. The safety and effectiveness of Enspryng in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Enspryng [package insert]. South San Francisco, CA: Genentech, Inc.; March 2022.