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5.99.019

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Miscellaneous Products	**Original Policy Date:**	September 25, 2020
Subject:	Enspryng	**Page:**	1 of 4

Last Review Date: March 6, 2026

Enspryng

Description

Enspryng (satralizumab-mwge)

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).

Related policies
Soliris, Uplizna

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Enspryng may be considered **medically necessary** if the conditions indicated below are met.

Enspryng may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Neuromyelitis optica spectrum disorder (NMOSD)

AND ALL of the following:

a. Anti-aquaporin-4 (AQP4) antibody positive
b. AST, ALT, and serum bilirubin will be assessed prior to initiating treatment with Enspryng
c. Prescriber agrees to monitor AST, ALT, and neutrophil counts

d. **NO** active hepatitis B infection
e. **NO** active or untreated latent tuberculosis
f. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Neuromyelitis optica spectrum disorder (NMOSD)

AND ALL of the following:
a. Patient has had fewer relapses while on Enspryng therapy
b. Prescriber agrees to monitor AST, ALT, and neutrophil counts
c. **NO** active hepatitis B infection
d. **NO** active or untreated latent tuberculosis
e. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 15 syringes

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 3 syringes per 84 days

Duration 12 months

Rationale

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.

Policy History

Date	Action
September 2020	Addition to PA
December 2020	Annual review
March 2021	Annual review
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.99.019
December 2023	Annual review
March 2024	Annual review
December 2024	Annual review
March 2025	Annual review
June 2025	Annual review
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.