| Effective date: 01/01/2021 |
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| Review date: 10/2020, 05/2021, 04/2022, 4/2023, 4/2024, 4/2025, 4/2026<br>Scope: Medicaid |

# ENSPRYNG (satralizumab-mwge)

## POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Enspryng is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

All other indications are considered experimental/investigational and not medically necessary.

### II. CRITERIA FOR INITIAL APPROVAL

**Neuromyelitis optica spectrum disorder (NMOSD)**
Authorization of 6 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:
A. Member is 18 years of age and older; AND
B. Documentation of anti-aquaporin-4 (AQPR) antibody positive; AND
C. Documentation that the member exhibits one of the following core clinical characteristics of NMOSD:
    1. Optic neuritis
    2. Acute myelitis
    3. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
    4. Acute brainstem syndrome
    5. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions; AND
D. Documentation that the diagnosis of multiple sclerosis or other diagnoses have been ruled out; AND
E. Documentation that the member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD; AND
F. Documentation that the member has a history of ≥ 1 relapses that required rescue therapy within the last 12 months prior to initiation of therapy; AND
G. Documentation that the member has an Expanded Disability Status Score (EDSS) of ≤ 6.5 (e.g., inability to take more than a few steps; restricted to wheelchair and may need aid in transferring; can wheel self but cannot carry on in standard wheelchair for a full day and may require a motorized wheelchair); AND
H. The prescribing physician must be a neurologist; AND

I. Submission of negative tuberculin tests prior to initiating therapy; AND
J. Documentation of baseline liver transaminase and neutrophil count is required prior to treatment; AND
K. Member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; AND
L. The prescribed dose and quantity fall within the FDA-approved labeling

## III. CONTINUATION OF THERAPY

Authorization of 6 months for continuation of therapy may be granted when both of the following criteria are met:

A. Documentation that the member demonstrates a positive response to therapy (e.g., reduction in number of relapses); AND
B. Documentation that the member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD; AND
C. Submission of liver transaminase and neutrophil count; AND
D. Documentation that the member has an Expanded Disability Status Score (EDSS) of ≤ 6.5 (e.g., inability to take more than a few steps; restricted to wheelchair and may need aid in transferring; can wheel self but cannot carry on in standard wheelchair for a full day and may require a motorized wheelchair); AND
E. The prescribing physician must be a neurologist; AND
F. The prescribed dose and quantity fall within the FDA-approved labeling

## IV. QUANTITY LIMIT

a. Loading dose: 3 syringes per 28 days
b. Maintenance dose: 1 syringe per 28 days

## V. REFERENCES

1. Enspryng [package insert]. South San Francisco, CA: Genentech, Inc.; December 2025.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015; 85:177-189.