

Effective date: 01/01/2021
Review date: 10/2020, 05/2021, 04/2022, 4/2023
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

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. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial requests: Immunoassay used to confirm anti-aquaporin-4 (AQP4) antibody is present.
- B. For continuation requests: Chart notes or medical documentation supporting positive clinical response

III. 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. Anti-aquaporin-4 (AQP4) antibody positive; AND
- C. 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. Diagnosis of multiple sclerosis or other diagnoses have been ruled out; AND

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- E. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD; AND
- F. The member has a history of ≥ 1 relapses that required rescue therapy within the last 12 months prior to initiation of therapy; AND
- G. Patient 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. Baseline liver transaminase and neutrophil count is required prior to treatment; AND
- K. Patient 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

IV. CONTINUATION OF THERAPY

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

- A. The member demonstrates a positive response to therapy (e.g., reduction in number of relapses); AND
- B. 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. Patient 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

V. QUANTITY LIMIT

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

VI. REFERENCES

1. Enspryng [package insert]. South San Francisco, CA: Genentech, Inc.; April 2022.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015; 85:177-189.