

Pharmacy Policy Bulletin

Title: Satralizumab-mwge (Enspryng®)

Policy #: Rx.01.237

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Satralizumab-mwge (Enspryng™)** as provided under the member's prescription drug benefit.

Description:

Neuromyelitis optica spectrum disorders (NMOSD), are inflammatory disorders of the central nervous system characterized by severe, immune-mediated demyelination and axonal damage predominantly targeting optic nerves and spinal cord. NMOSD can be distinguished from multiple sclerosis and other central nervous system inflammatory disorders by the unique presence of the disease-specific aquaporin-4 (AQP4) antibody, which plays a direct role in the pathogenesis of NMOSD.

Common features of NMOSD include acute attacks characterized by bilateral or rapidly sequential optic neuritis (leading to visual loss), acute transverse myelitis (often causing limb weakness and bladder dysfunction), and the area postrema syndrome (with intractable hiccups or nausea and vomiting).

The precise mechanism by which Satralizumab-mwge (Enspryng™) exerts therapeutic effects in NMOSD is unknown but is presumed to involve inhibition of IL-6-mediated signaling through binding to soluble and membrane-bound IL-6 receptors. Satralizumab-mwge (Enspryng™) is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Policy:

INITIAL CRITERIA: Satralizumab-mwge (Enspryng™) is approved when ALL of the following are met:

1. Diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and
2. Member is anti-aquaporin-4 (AQP4) antibody positive; and
3. Prescribed by or in consultation with a neurologist or ophthalmologist; and
4. Member is 18 years of age or older

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Satralizumab-mwge (Enspryng™) is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Enspryng™ (satralizumab-mwge) [prescribing information]. San Francisco, CA: Genentech, Inc; March 2022. Available from: https://www.gene.com/download/pdf/enspryng_prescribing.pdf. Accessed April 20, 2023.

Glisson C. Neuromyelitis optica spectrum disorders. UpToDate website. Last updated August 2022. Available at: www.uptodate.com. Accessed April 20, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Enspryng™	Satralizumab-mwge

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	3.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	March 16, 2024

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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