Effective Date **3/15/2024**
Next Review Date **3/15/2025**
Coverage Policy Number **IP0078**

Satralizumab-mwge

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for satralizumab-mwge (**Enspryng**®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Satralizumab-mwge (Enspryng) is considered medically necessary when the following are met:

Neuromyelitis Optica Spectrum Disorder (NMOSD). Individual meets **ALL** of the following criteria:

A. Age 18 years or older
B. Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by blood serum test for anti-aquaporin-4 antibody positive
C. Documentation of failure, contraindication, or intolerance to rituximab (prior authorization may apply)

An exception to the requirement of systemic therapy can be made if there has been failure to Soliris® (eculizumab injection) or Uplizna® (inebilizumab-cdon injection) for neuromyelitis optica spectrum disorder.

D. Medication is prescribed by, or in consultation with, a neurologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of satralizumab-mwge (Enspryng) is considered medically necessary for neuromyelitis optica spectrum disorder (NMOSD) when the above medical necessity criteria are met AND there is documentation of beneficial response (for example, reduction in relapse rate, reduction in symptoms, a slowing progression in symptoms).

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Concomitant Use with a Rituximab Product, Soliris (eculizumab intravenous infusion), or Uplizna (inebilizumab-cdon intravenous infusion). There is no evidence to support concomitant use of Enspryng with a rituximab product, Soliris or Uplizna.

Background

OVERVIEW
Enspryng, an interleukin-6 receptor antagonist, is indicated for the treatment of **neuromyelitis optica spectrum disorder** (NMOSD) in adults who are anti-aquaporin-4 antibody positive.[1]

Disease Overview
NMOSD is a rare, relapsing, autoimmune disorder of the brain and spinal cord with optic neuritis and/or myelitis as predominant characteristic symptoms.[2] NMOSD often causes significant, permanent damage to vision and/or spinal cord function resulting in blindness or impaired mobility.[3] Patients may experience pain, paralysis, loss of bowel and bladder control, loss of visual acuity, and uncontrolled motor functions. Complications can lead to death.

Other Therapies
Soliris® (eculizumab intravenous infusion) and Uplizna™ (inebilizumab-cdon intravenous infusion) are two other FDA-approved medications for treatment of NMOSD.[4,5] For acute attacks, typical treatment is high-dose intravenous corticosteroids.[6,7] Plasma exchange may be effective in patients who suffer acute severe attacks that do not respond to intravenous corticosteroids. For long-term control of the disease, a variety of immunosuppressive drugs are utilized as first-line therapy. Preventative maintenance therapies include corticosteroids, azathioprine, mycophenolate mofetil, and rituximab (off-label).

References

1. Enspryng subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; March 2022.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Updated July 2022. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed September 18, 2023.
3. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015;85(2):177-189.
4. Soliris® intravenous infusion [prescribing information]. Boston, MA: Alexion; November 2020.
5. Uplizna® intravenous infusion [prescribing information]. Gaithersburg, MD: Viela Bio; July 2021.
6. Bradshaw M and Kimbrough D. Neuromyelitis Optica Spectrum Disorders. *Practical Neurology*. 2019;76-84.
7. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. Available at: https://wearesrna.org/wp-content/uploads/2018/06/About_NMOSD_2018.pdf. Accessed on September 18, 2023.