Clinical Criteria

Subject:	Enspryng (satralizumab-mwge)		
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Overview

This document addresses the use of Enspryng (satralizumab-mwge), a humanized monoclonal antibody directed against IL-6 receptors. Enspryng is approved for treatment of neuromyelitis optica spectrum disorder (NMSOD).

NMOSD is a severe autoimmune disease of the central nervous system caused by immune-mediated demyelination and axonal damage predominantly targeting optic nerves and spinal cord. This damage is triggered by antibodies against aquaporin-4 (AQP4), which are considered biomarkers for NMOSD. The disease is characterized by clusters of attacks of optic neuritis or transverse myelitis with partial recovery between attacks. Progressive visual impairment and paralysis may be caused by repeated attacks, so long-term prevention therapy should be offered to all patients. Treatment may include off label immunosuppressive therapies including rituximab, azathioprine, and mycophenolate. Three agents are FDA approved for NMOSD: Enspryng, Uplizna and Soliris. Enspryng has a unique mechanism of action by suppressing inflammation triggered by IL-6 pathways. It is given via subcutaneous administration once every 4 weeks. It has demonstrated efficacy in combination with stable immunosuppressive therapy and as monotherapy in AQP4 seropositive individuals. To date there is insufficient evidence to support its use in seronegative individuals.

Enspryng can increase the risk of infection, as it is an immunosuppressant. It is contraindicated in those with active hepatitis B (HBV) infection and those with active or untreated latent tuberculosis (TB). Prior to initiation of therapy, all individuals should receive HBV screening, TB screening, and assessment of liver transaminases and serum bilirubin. Individuals should also receive all immunizations according to guidelines prior to initiating therapy.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Enspryng (satralizumab-mwge)

Requests for initiation of therapy with Enspryng (satralizumab-mwge) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); **AND**
III. Documentation is provided that NMOSD is seropositive as confirmed by the presence of anti- aquaporin-4 (AQP4) antibodies; **AND**
IV. Documentation is provided that individual has a history of at least 1 acute attack or relapse in the last 12 months prior to initiation of therapy (Yamamura 2019, Traboulsee 2020).

Requests for continued use of Enspryng (satralizumab-mwge) in NMOSD may be approved if the following criteria are met:

I. Documentation is provided that individual has experienced a clinical response (for example, a reduction in the frequency of relapse).

Requests for Enspryng (satralizumab-mwge) may not be approved for the following:

I. All other indication not included above; **OR**
II. Individual is using in combination with rituximab, eculizumab, or inebilizumab; **OR**

III. Individual has active hepatitis B (HBV) infection; **OR**
IV. Individual has active or untreated latent tuberculosis.

Initial and Continuation Approval Duration: 1 year

Quantity Limits

Enspryng (satralizumab-mwge) Quantity Limit

Drug	Limit
Enspryng (satralizumab-mwge) 120 mg/mL prefilled syringe	1 syringe per 28 days
Override Criteria	
*Initiation of therapy for neuromyelitis optica spectrum disorder (NMOSD): May approve one additional syringe (120 mg/mL) in the first 28 days (4 weeks) of treatment	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3490	Unclassified drugs (when specified as [Enspryng] (satralizumab-mwge)
J3590	Unclassified biologics (when specified as [Enspryng] (satralizumab-mwge)
C9399	Unclassified drugs or biologicals (when specified as [Enspryng] (satralizumab-mwge)

ICD-10 Diagnosis

All diagnoses

Document History

Reviewed: 11/19/2021
Document History:

- 11/19/2021 – Annual Review: Clarify approval durations; update may not approve criteria to include combination use with other NMOSD agents. Coding Reviewed: Added HCPCS C9399.
- 08/01/2021 – Administrative update to add documentation.
- 11/20/2020 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/21/2020 – Select Review: Add new clinical criteria document for Enspryng. Coding reviewed: Added HCPCS J3490, J3590. All Diagnoses pend

References

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N Engl J Med. 2019 Nov 28;381(22):2114-2124. doi: 10.1056/NEJMoa1901747.
6. Traboulsee A, Greenberg BM, Bennett JL, et al. Safety and efficacy of satralizumab monotherapy in neuromyelitis optica spectrum disorder: a randomised, double-blind, multicentre, placebo-controlled phase 3 trial. *Lancet Neurol*. 2020;19(5):402-412.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.