Clinical Criteria

Subject:	Enspryng (satralizumab-mwge)		
Document #:	ING-CC-0173	Publish Date:	09/01/2020
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Table of Contents

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. Enspryng approval follows that of Uplizna and Soliris. Enspryng has a unique mechanism of action by suppressing inflammation triggered by IL-6 pathways. It will be 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 (satralizumab-mwge) is contraindicated in individuals with active hepatitis B infection and active or untreated latent tuberculosis.

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. NMOSD is seropositive as confirmed by the presence of anti- aquaporin-4 (AQP4) antibodies; AND
IV. Individual has a history of at least 1 relapse in the last 12 months prior to initiation of therapy (Yamamura 2019, Traboulsee 2020).

Initial Approval Duration: 1 year

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

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

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)

ICD-10 Diagnosis

All diagnosis

Document History

New: 08/21/2020
Document History:

- 08/21/2020 – Select Review: Add new clinical criteria document for Enspryng. Coding reviewed: Added HCPCS J3490, J3590. All Diagnosis pend

References

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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.
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