

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Enspryng (satralizumab-mwge)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Enspryng (satralizumab-mwge) 120 mg/mL prefilled syringe	1 syringe per 28 days*

***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

APPROVAL CRITERIA

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).

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.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 7, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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 policies may take precedence over the application of this clinical criteria.

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