



Enspryng™ (satralizumab-mwge) (Subcutaneous)

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I. Length of Authorization

Initial coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Enspryng 120 mg/mL single-dose prefilled syringe

- Loading Doses: 1 syringe on day 1, 15, 29
- Maintenance Dose: 1 syringe every 4 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

- 120 mg on days 1, 15, 29 and then 120 mg every 4 weeks thereafter

III. Initial Approval Criteria ^{1,2,3}

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; **AND**
- Patient has not received any live or live-attenuated vaccinations in the 4-weeks prior to or non-live vaccinations in the 2-weeks prior to, the start of therapy; **AND**

Universal Criteria ^{1,2,3}

- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Will not be administered concurrently with live vaccines; **AND**

- Patient is not on concomitant therapy with, and does not have hypersensitivity to, other interleukin-6 (IL-6) receptor antagonists (i.e., tocilizumab, sarilumab, etc.); **AND**
- Patients has not previously received, and will not concomitantly receive therapy with, other drugs which can result in prolonged additive immunosuppression (e.g., alemtuzumab, cladribine, cyclophosphamide, or mitoxantrone) [Note: concomitant therapy with corticosteroids and/or immunosuppressants such as azathioprine or mycophenolate are allowed] **OR** other immunosuppressant procedures (i.e., total lymphoid irradiation, bone marrow transplant); **AND**
- Patient has not received therapy within the prior 6 months with any of the following:
 - Anti-BLyS monoclonal antibody (e.g., belimumab); **OR**
 - Therapies for prevention of multiple sclerosis (MS) relapse (i.e., interferon, natalizumab, glatiramer acetate, fingolimod, teriflunomide or dimethyl fumarate); **AND**
- Patient will not concomitantly receive therapy with any of the following:
 - Complement-inhibitors (e.g., eculizumab, ravulizumab); **OR**
 - Anti-CD20-directed antibody (e.g., rituximab); **OR**
 - Anti-CD19-directed antibody (e.g., inebilizumab); **AND**

Neuromyelitis Optica Spectrum Disorder (NMOSD) † Φ ^{1,2,3,4}

- Patient has a confirmed diagnosis based on the following:
 - Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
 - Patient has at least one core clinical characteristic §; **AND**
 - Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); **AND**
- Patient has a history of one or more relapses that required rescue therapy within the prior year or two or more relapses that required rescue therapy within the prior 2 years; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 6.5 (i.e., requires two walking aids – pair of canes, crutches, etc. – to walk about 20m without resting); **AND**
- Patient is at risk of having a disabling relapse of NMOSD for which oral agents (e.g. corticosteroids and immunosuppressants such as azathioprine and mycophenolate) alone are inadequate and biologic therapy is necessary

§ Core Clinical Characteristics of NMOSD ⁴

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome

- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,2,3}

Coverage may be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, serious infections, severe hepatotoxicity, severe neutropenia, etc.; **AND**
- Disease response as indicated by stabilization/improvement in any of the following: neurologic symptoms as evidenced by a decrease in acute relapses, stability, or improvement in EDSS, reduced hospitalizations, reduction/discontinuation in plasma exchange treatments, and/or reduction/discontinuation of corticosteroids without relapse

V. Dosage/Administration

Indication	Dose
Neuromyelitis Optica Spectrum Disorder (NMOSD)	The recommended loading dosage of Enspryng for the first three administrations is 120 mg by subcutaneous injection at Weeks 0, 2, and 4, followed by a maintenance dosage of 120 mg every 4 weeks.
<p>– <i>Enspryng is intended for patient self-administration by subcutaneous injection under the guidance of a health care professional (HCP). After proper training in subcutaneous injection technique, a patient may self-inject Enspryng or the patient's caregiver may administer Enspryng, if the HCP determines that it is appropriate.</i></p> <p>– <i>Prior to use, remove the prefilled syringe from the refrigerator and allow to sit at room temperature outside of the carton for 30 minutes. Do not warm ENSPRYNG in any other way.</i></p>	

VI. Billing Code/Availability Information

HCPCS code:

J3590 – Unclassified biologics

NDC:

Enspryng 120 mg/mL single-use pre-filled syringe: 50242-0007-xx

VII. References

1. Enspryng [package insert]. South San Francisco, CA; Genentech, Inc; August 2020. Accessed August 2020.

2. 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 May;19(5):402-412. doi: 10.1016/S1474-4422(20)30078-8.
3. 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.
4. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology* Jul 2015, 85 (2) 177-189; DOI: 10.1212/WNL.0000000000001729

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G36.0	Neuromyelitis optica [Devic]

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Article (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at:

<http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

ENSPRYNG™ (satralizumab-mwge) Prior Auth Criteria

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