MEDICAL MUTUAL®

Drug Policy

Policy:	**2020901**	**Initial Effective Date: 11/06/2020**
Code(s):	**HCPCS J3590, C9399**	**Annual Review Date: 10/19/2022**
SUBJECT:	**Enspryng™ (satralizumab-mwge) (Subcutaneous)**	**Last Revised Date: 10/19/2023**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

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 [1-3]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed to be negative for active HBV; **AND**

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Universal Criteria [1-3]

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Live or live-attenuated vaccinations will not be administered within the 4-weeks prior to the start of therapy and will not be administered concurrently while on treatment; **AND**
- Patient is not on concomitant therapy with, and does not have hypersensitivity to, other interleukin-6 (IL-6) receptor antagonists (e.g., tocilizumab, sarilumab, etc.); **AND**
- Patient has not previously received, and will not concomitantly receive, therapy with any of the following:
    - 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];* **AND**
    - Other immunosuppressant procedures (i.e., total body 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); **AND**
    - Therapies for prevention of multiple sclerosis (MS) relapse (e.g., 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); **AND**
    - Anti-CD20-directed antibody (e.g., rituximab); **AND**
    - Anti-CD19-directed antibody (e.g., inebilizumab); **AND**

Neuromyelitis Optica Spectrum Disorder (NMOSD) † Φ [1-5]

- 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 **§** *(Note: some core clinical characteristics require both clinical and typical MRI findings)*; **AND**
    - Alternative diagnoses have been excluded [e.g., myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD), 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**

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- 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 [5]
▪ Acute optic neuritis ▪ Acute myelitis ▪ Area postrema syndrome (APS): episode of otherwise unexplained hiccups and/or nausea and vomiting (lasting for at least 48 hours or with MRI evidence of a dorsal brainstem lesion) ▪ Acute brainstem syndrome other than APS ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesion on MRI ¥ ▪ Acute cerebral syndrome with NMOSD-typical brain lesion on MRI ψ
¥ Diencephalic syndrome: Periependymal lesion (3rd ventricle) OR hypothalamic/thalamic lesion ψ Cerebral syndrome: Extensive periependymal lesion (lateral ventricle; often with Gd) OR long (> 1⁄2 length), diffuse, heterogeneous or edematous corpus callosum lesion OR long corticospinal tract lesion (unilateral or bilateral, contiguously involving internal capsule and cerebral peduncle) OR large, confluent (unilateral or bilateral) subcortical or deep white matter lesion

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1-3]

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: severe hypersensitivity reactions, serious infections, elevated liver enzymes, severe neutropenia, etc.; **AND**
- Disease response as indicated by stabilization/improvement in one or more of the following:
    - Neurologic symptoms as evidenced by a decrease in acute relapses, improvement in stability, or improvement in EDSS
    - Reduced hospitalizations
    - Reduction/discontinuation in plasma exchange treatments
    - Reduction/discontinuation of corticosteroids without relapse

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V. Dosage/Administration [1]

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.

- *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.*
- *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.*

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use Only)*

NDC:

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

VII. References

1. Enspryng [package insert]. South San Francisco, CA; Genentech, Inc; March 2022. Accessed September 2023.
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.
5. Jarius, S., Aktas, O., Ayzenberg, I. et al. Update on the diagnosis and treatment of neuromyelits optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part I: Diagnosis and differential diagnosis. J Neurol 270, 3341–3368 (2023). https://doi.org/10.1007/s00415-023-11634-0.

Appendix 1 – Covered Diagnosis Codes

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

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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: https://www.cms.gov/medicare-coverage-database/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		
Jurisdictio	**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,	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	Novitas Solutions, Inc.
K (13 &	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

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Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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