UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2222-5
Program	Prior Authorization/Medical Necessity
Medications	Enspryng™ (satralizumab-mwge)
P&T Approval Date	10/2020, 10/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Enspryng (satralizumab-mwge) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Enspryng** will be approved based on **all** of the following criteria:

   a. Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

   -AND-

   b. Patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies

   -AND-

   c. History of failure, contraindication, or intolerance to rituximab therapy

   -AND-

   d. **One** of the following:

      (1) History of one or more relapses that required rescue therapy during the previous 12 months

      -OR-

      (2) History of two or more relapses that required rescue therapy during the previous 24 months

      -AND-

   e. Prescribed by, or in consultation with, a neurologist

   -AND-

f. Patient is not receiving Enspryng in combination with any of the following:

(1) Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
(2) Complement inhibitors [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), etc.]
(3) Anti-IL6 therapy [e.g., Actemra (tocilizumab)]
(4) B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumb-cdon)]

Authorization will be issued for 12 months.

B. Reauthorization

1. **Enspryng** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response to Enspryng therapy

-AND-

b. Prescribed by, or in consultation with, a neurologist

-AND-

c. Patient is not receiving Enspryng in combination with any of the following:

(1) Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
(2) Complement inhibitors [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), etc.]
(3) Anti-IL6 therapy [e.g., Actemra (tocilizumab)]
(4) B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumb-cdon)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Enspryng [package insert]. South San Francisco, CA: Genentech, Inc.; March 2022.
2. Sellner J1, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. Eur J Neurol. 2010 Aug;17(8):1019-32.
3. Sato D, Callegaro D, Lana-Peixoto MA, Fujihara K. Treatment of neuromyelitis optica: an evidencebased review. Arq Neuropsiquiatr 2012;70(1);59-66.

4. Ciron J, Audoin B, Bourre B, et al. Recommendations for the use of rituximab in neuromyelitis optica spectrum disorders. Rev Neurol (Paris). 2018 Apr;174(4):255-264.
5. Nikoo Z, Badihian S, Shaygannejad V, et al. Comparison of the efficacy of azathioprine and rituximab in neuromyelitis optica spectrum disorder: a randomized clinical trial. J Neurol. 2017 Sep;264(9):2003-2009.
6. Gao F, Chai B, Gu C, et al. Effectiveness of rituximab in neuromyelitis optica: a meta-analysis. BMC Neurol. 2019 Mar 6;19(1):36.
7. Kim SH, Huh SY, Lee SJ, et al. A 5-year follow-up of rituximab treatment in patients with neuromyelitis optica spectrum disorder. JAMA Neurol. 2013 Sep 1;70(9):1110-7.
8. Yamamura T, Kleiter I, Fujihara K, et al. Trial of satralizumab in neuromyelitis optica spectrum disorder. N Engl J Med. 2019;381(22):2114-2124.
9. 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.

Program	Prior Authorization/Medical Necessity – Enspryng (satralizumab-mwge)
Change Control	
10/2020	New program.
10/2021	Annual review with no changes to clinical criteria.
10/2022	Annual review with no changes to clinical criteria. Updated reference.
10/2023	Annual review with no changes.
10/2024	Annual review with no changes to clinical criteria. Updated examples of complement inhibitors.