UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1331-5
Program	Prior Authorization/Notification
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. 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 **both** of the following criteria:

   a. Documentation of positive clinical response to Enspryng therapy

   -AND-

   b. 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.
- Medical Necessity, Supply limits may be in place.

4. References:

1. Enspryng [package insert]. South San Francisco, CA: Genentech, Inc.; March 2022.

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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. Added state mandate footnote. Updated reference.
10/2023	Annual review. No changes.
10/2024	Annual review. No changes to coverage criteria. Updated examples of complement inhibitors.