

PRIOR AUTHORIZATION POLICY

POLICY: Enspryng Prior Authorization Policy

- Enspryng® (satralizumab-mwge subcutaneous injection – Genentech)

REVIEW DATE: 04/10/2024

OVERVIEW

Enspryng, an interleukin-6 receptor antagonist, is indicated for the treatment of **neuromyelitis optica spectrum disorder** (NMOSD) in adults who are anti-aquaporin-4 antibody positive.¹

Disease Overview

NMOSD is a rare, relapsing, autoimmune disorder of the brain and spinal cord with optic neuritis and/or myelitis as predominant characteristic symptoms.² NMOSD often causes significant, permanent damage to vision and/or spinal cord function resulting in blindness or impaired mobility.³ Patients may experience pain, paralysis, loss of bowel and bladder control, loss of visual acuity, and uncontrolled motor functions. Complications can lead to death.

Recommendations

The Neuromyelitis Optica Study Group (NEMOS) published revised recommendations for the treatment of NMOSD in 2024.⁴ The standard of care for the treatment of NMOSD attacks (for both AQP4-IgG-positive and double-negative cases) are high-dose glucocorticoids and/or apheresis therapy. Long-term immunotherapy is recommended for patients with AQP4-IgG-positive NMOSD. NEMOS notes the first-choice therapies for the treatment of AQP4-IgG-positive NMOSD are Enspryng, Soliris® (eculizumab intravenous infusion), Ultomiris® (ravulizumab-cwyz intravenous infusion), Uplizna® (inebilizumab-cdon intravenous infusion), and rituximab. The order of preference for these therapies is unclear and further comparative trials and real-world data are needed. The choice of treatment is dependent on several factors, including disease activity and severity, mode and onset of action, possibility to combine it with immunosuppressive drugs, effect on autoimmune and other comorbidities, gender (family planning issues), frequency and route of administration, side effect profile as well as patient and physician preference. In general, if a patient fails a first-choice treatment, another first-choice treatment should be tried; other options include use of a second-choice treatment (azathioprine, mycophenolate mofetil, low-dose oral glucocorticoids) or the addition of a second-choice treatment to the regimen.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Enspryng. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Enspryng as well as the monitoring required for adverse events and long-term efficacy, approval requires Enspryng to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Enspryng is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Neuromyelitis Optica Spectrum Disorder.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) **Initial Therapy.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is \geq 18 years of age; AND
 - ii. Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND
 - iii. The medication is being prescribed by or in consultation with a neurologist.
 - B) **Patient is Currently Receiving Enspryng.** Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
 - i. Patient is \geq 18 years of age; AND
 - ii. Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND
 - iii. According to the prescriber, patient has had clinical benefit from the use of Enspryng; AND
Note: Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function), and a slowing in progression of symptoms.
 - iv. The medication is being prescribed by or in consultation with a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Enspryng is not recommended in the following situations:

1. **Concomitant Use with a Rituximab Product, Soliris (eculizumab intravenous infusion), Ultomiris (ravulizumab-cwyz intravenous infusion), or Uplizna (inebilizumab-cdon intravenous infusion).** There is no evidence to support concomitant use of Enspryng with a rituximab product, Soliris, Ultomiris, or Uplizna.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Enspryng[®] subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; March 2022.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Updated July 2022. Available at: <https://rarediseases.org/rare-diseases/neuromyelitis-optica/>. Accessed April 5, 2024.
3. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015;85(2):177-189.
4. Kämpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. *J Neurol*. 2024;271:141-176.

