PRIOR AUTHORIZATION POLICY

POLICY: Enspryng Prior Authorization Policy
- Enspryng® (satralizumab-mwge subcutaneous injection – Genentech)

REVIEW DATE: 08/31/2022

OVERVIEW
Enspryng, an interleukin-6 receptor antagonist, is indicated for the treatment of **neuromyelitis optica spectrum disorder** (NMOSD) in patients ≥ 18 years of age 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.

Other Therapies
Soliris® (eculizumab intravenous infusion) and Uplizna™ (inebilizumab-cdon intravenous infusion) are two other FDA-approved medications for treatment of NMOSD.[4,5] For acute attacks, typical treatment is high-dose intravenous corticosteroids.[6,7] Plasma exchange may be effective in patients who suffer acute severe attacks that do not respond to intravenous corticosteroids. For long-term control of the disease, a variety of immunosuppressive drugs are utilized as first-line therapy. Preventative maintenance therapies include corticosteroids, azathioprine, mycophenolate mofetil, and rituximab (off-label).

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 if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets the following criteria (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Neuromyelitis optica spectrum disorder diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND

iii. Patient is currently receiving or has previously tried TWO of the following systemic therapies (a, b, c, or d):
- **a)** Azathioprine; OR
- **b)** Corticosteroid; OR
- **c)** Mycophenolate mofetil; OR
- **d)** Rituximab; AND

Note: An exception to the requirement for a trial of a systemic therapy can be made if the patient has already tried Soliris (eculizumab intravenous infusion) or Uplizna (inebilizumab-cdon intravenous infusion) for neuromyelitis optica spectrum disorder. Patients who have already tried Soliris or Uplizna for neuromyelitis optica spectrum disorder are not required to try another systemic agent.

iv. Patient has a of at least one relapse in the last 12 months or two relapses in the last 2 years; AND

v. 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 the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Neuromyelitis optica spectrum disorder 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), or Uplizna (inebilizumab-cdon intravenous infusion).** There is no evidence to support additive efficacy of combining Enspryng with rituximab, Soliris 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; July 2021.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed August 18, 2022.
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. Soliris® intravenous infusion [prescribing information]. Boston, MA: Alexion; July 2022.
5. Uplizna® intravenous infusion [prescribing information]. Gaithersburg, MD: Viela Bio; July 2021.
6. Bradshaw M and Kimbrough D. Neuromyelitis Optica Spectrum Disorders. *Practical Neurology*. 2019;76-84.
7. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. Available at: https://wearesrna.org/wp-content/uploads/2018/06/About_NMOSD_2018.pdf. Accessed on August 18, 2022.