VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Enspryng Prior Authorization Policy
- Enspryng™ (satralizumab-mwge for subcutaneous injection – Viela Bio)

REVIEW DATE: 08/26/2020; selected revision 09/09/2020

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 predominate 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, uncontrolled motor functions, and complications can lead to death.

Other Therapies
Soliris® (eculizumab injection for intravenous infusion) and Uplizna™ (inebilizumab-cdon injection for intravenous infusion) are two other FDA-approved medications for treatment of NMOSD in adults who are anti-AQP4 antibody-positive.[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 Indications

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 blood serum test for anti-aquaporin-4 antibody positive; 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 injection) or Uplizna™ (inebilizumab-cdon injection) 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 history 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 blood serum test for anti-aquaporin-4 antibody positive; 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 progression in 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 injection), or Uplizna™ (inebilizumab-cdon injection).** 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™ injection [prescribing information]. South San Francisco, CA: Genentech; August 2020.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed August 17, 2020.
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® injection [prescribing information]. Boston, MA: Alexion Pharmaceuticals; June 2019.
5. Uplizna™ injection [prescribing information]. Gaithersburg, MD: Viela Bio, Inc; June 2020.
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 17, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/26/2020
Selected Revision	**Neuromyelitis Optica Spectrum Disorder.** Initial therapy approval duration was changed from 6 months to 1 year. The requirement for tried systemic therapies verbiage of "used in the maintenance setting" was removed. The addition of two relapses in the last 2 years was added as an option and (acute attack from neuromyelitis optica spectrum disorder) was removed from the history of relapses criteria. **Concomitant use with Soliris® (eculizumab injection) or Uplizna™ (inebilizumab-cdon injection).** Rituximab was added as a product not to be used concomitantly with Enspryng.	09/09/2020