PRIOR AUTHORIZATION POLICY

POLICY: Uplizna Prior Authorization Policy
- Uplizna® (inebilizumab-cdon intravenous infusion – Viela Bio)

REVIEW DATE: 06/29/2022

OVERVIEW

Uplizna, a CD19-directed cytolytic antibody, 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] The recommended dose is 300 mg administered as an intravenous infusion under the close supervision of an experienced healthcare professional. The initial infusion is followed 2 weeks later by a second infusion. Starting 6 months from the first infusion, subsequent doses are administered once every 6 months.

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 causing 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 cause death. Soliris® (eculizumab intravenous infusion) and Enspryng™ (satralizumab-mwge subcutaneous injection) 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 response to intravenous corticosteroids. For long-term control of the disease a variety of immunosuppressive drugs are utilized as first-line therapy. While all are considered off-label use, corticosteroids, azathioprine, mycophenolate mofetil, and rituximab are treatments prescribed as preventative therapy.

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Uplizna 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.** Diagnosis of neuromyelitis optica spectrum disorder 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 intravenous infusion) or Enspryng™ (satralizumab-mwge subcutaneous injection) for neuromyelitis optica spectrum disorder. Patients who have already tried Soliris or Enspryng for neuromyelitis optica spectrum disorder are not required to try another systemic agent.
     - **iv.** Patient has a of at least 1 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 Uplizna. Approve for 1 year if the patient meets the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Diagnosis of neuromyelitis optica spectrum disorder 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 Uplizna; 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 Uplizna is not recommended in the following situations:

1. **Concomitant Use With a Rituximab Product, Soliris (eculizumab intravenous infusion), or Enspryng™ (satralizumab-mwge subcutaneous injection).** There is no evidence to support additive efficacy of combining Uplizna with rituximab, Soliris, or Enspryng.

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. Uplizna® intravenous infusion [prescribing information]. Gaithersburg, MD: Viela Bio; December 2020.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed June 24, 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. Enspryng™ subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; July 2020.
5. Soliris® intravenous infusion [prescribing information]. Boston, MA: Alexion; April 0221.
6. Bradshaw M and Kimbrough D. Neuromyelitis Optica Spectrum Disorders. *Practical Neurology*. 2019;76-84.
7. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. https://wearesrna.org/wp-content/uploads/2018/06/About_NMOSD_2018.pdf. Accessed June 24, 2022.