VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Uplizna Utilization Review Medical Policy
- Uplizna™ (inebilizumab-cdon injection for intravenous use – Viela Bio)

REVIEW DATE: 06/24/2020

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 for intravenous use), a complement inhibitor, is the only other FDA-approved medication for treatment of NMOSD in adult patients who are anti-aquaporin-4 antibody positive.[4] For acute attacks, typical treatment is high-dose intravenous corticosteroids.[5,6] 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 by providers 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 medical benefit coverage of Uplizna. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Neuromyelitis Optica Spectrum Disorder**. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive; AND
   - **C)** Patient has previously tried one of the following systemic therapies (i, ii, iii, iv, or v):
     - **i.** Azathioprine
     - **ii.** Corticosteroid
     - **iii.** Mycophenolate mofetil
     - **iv.** Rituximab
     - **v.** Soliris (eculizumab for intravenous use)
   - **D)** Uplizna is being prescribed by or in consultation with a neurologist.

   Dosing. Approve the following dosing regimens (A or B):
   - **A)** 300 mg by intravenous infusion once every 2 weeks for 2 doses; OR
   - **B)** 300 mg by intravenous infusion once every 6 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Uplizna is not recommended in the following situations:

1. 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™ injection [prescribing information]. Gaithersburg, MD: Viela Bio, Inc; June 2020.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed June 16, 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. Bradshaw M and Kimbrough D. Neuromyelitis Optica Spectrum Disorders. *Practical Neurology*. 2019;76-84.
6. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. https://wearesrna.org/wp-content/uploads/2018/06/About_NMOSD_2018.pdf. Accessed June 19, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/24/2020