Utilization Review Policy 232

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

EFFECTIVE DATE: 12/1/2020
LAST REVISION DATE: 07/12/2023

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Uplizna, a CD19-directed cytolytic antibody, is indicated for the treatment of **neuromyelitis optica spectrum disorder** (NMOSD) in adults who are anti-aquaporin-4 antibody-positive.[1] The recommended dose is 300 mg administered as an intravenous (IV) infusion under the close supervision of an experienced healthcare professional. The initial infusion is followed 2 weeks later by a second 300 mg IV infusion. Subsequent doses are administered once every 6 months (starting 6 months after the first infusion).

Disease Overview

NMOSD is a rare, relapsing, autoimmune central nervous system inflammatory disorder that can lead to significant morbidity and mortality.[2,3] The predominant symptoms are inflammation of the optic nerve (optic neuritis) and inflammation of the spinal cord (myelitis). Optic neuritis may lead to pain inside the eye and can progress to blindness. Myelitis tends to affect some, and often all, motor, sensory, and autonomic functions (bladder and bowel). Affected patients may experience pain in the spine or limbs, mild to severe paralysis of the lower limbs, and loss of bowel and bladder control. For acute attacks, typical treatment is high-dose intravenous corticosteroids.[2] Plasma exchange may be effective in patients who suffer acute severe attacks and who do not respond to intravenous corticosteroids. For long-term control of the disease (relapse prevention), a variety of immunosuppressive drugs are utilized as first-line therapy; most widely prescribed are corticosteroids, azathioprine, mycophenolate mofetil, and rituximab. Interleukin-6 signaling blocking agents (e.g., Enspryng® [satralizumab-mwge subcutaneous {SC} injection], Actemra [tocilizumab injection for IV or SC use]), Soliris® (eculizumab IV infusion), and IV immunoglobulins are also used for relapse prevention.[3] Note that of the listed agents, only Enspryng and Soliris are FDA-approved for NMOSD.[4,5]

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.

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 (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets the following (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 disease; 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 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 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 disease; 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.

   Dosing. Approve the following dosing regimens (A or B):
   - **A)** 300 mg by intravenous infusion once every 2 weeks for two 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. **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]. Deerfield, IL: Horizon Therapeutics; July 2021.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Last updated July 27, 2022. Available at: https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed on July 7, 2023.
3. Chan KH, Lee CY. Treatment of neuromyelitis optica spectrum disorders. *Int J Mol Sci*. 2021;22(16):8638.
4. Enspryng® subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; March 2022.
5. Soliris® intravenous infusion [prescribing information]. Boston, MA: Alexion; November 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/06/2022
Annual Revision	No criteria changes.	07/12/2023