Inebilizumab-cdon (Uplizna®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration HCPCS: **J1823** per 1 mg

Condition listed in policy (*see criteria for details*)

- Neuromyelitis optica spectrum disorder (NMOSD)

AHFS therapeutic class: Immunomodulatory agent

Mechanism of action: CD19-directed cytolytic antibody

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for inebilizumab-cdon (Uplizna®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Neuromyelitis optica spectrum disorder (NMOSD)

1. Prescribed by or in consultation with by a neurologist, **AND**
2. Positive for anti-aquaporin-4 (AQP4) antibodies, **AND**
3. ***Effective 1/28/2024 and after***: Not being used in combination with another drug therapy for NMOSD (e.g., rituximab, eculizumab, satralizumab), **AND**
4. Meets one of the following:
    a. Patient has had an inadequate response or intolerance to rituximab, or
    b. Patient has not been treated with rituximab AND has a contraindication to Ruxience, Riabni and Truxima

Covered Dose
Initial: Up to 300 mg given intravenously for one dose, followed by 300 mg two weeks later. A third dose of 300 mg is given 6 months from the first infusion.
Reauthorization: Up to 300 mg given intravenously every 6 months

Coverage Period
Initial: For the first 3 doses
Reauthorization: Yearly, with documented reduction in frequency of NMO attacks from baseline

ICD-10:
G36.0

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for inebilizumab-cdon (Uplizna®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 100 mg/10 mL (10 mg/mL) solution in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Uplizna® (inebilizumab-cdon) [Prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; 7/2021.

(7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024
Changes from previous policy version:

- Section (2): Neuromyelitis optica spectrum disorder (NMOSD) – *Effective 1/28/2024* and after, combination use with other drug therapies indicated for neuromyelitis optica spectrum disorder will be managed
  Rationale: Uplizna prescribing information

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee