

# SPECIALTY GUIDELINE MANAGEMENT

## UPLIZNA (inebilizumab-cdon)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Uplizna is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial requests: Immunoassay used to confirm anti-aquaporin-4 (AQP4) antibody is present.
- B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

#### III. CRITERIA FOR INITIAL APPROVAL

##### **Neuromyelitis optica spectrum disorder (NMOSD)**

- A. Authorization of 12 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:
  - 1. Anti-aquaporin-4 (AQPR) antibody positive
  - 2. Member exhibits one of the following core clinical characteristics of NMOSD:
    - i. Optic neuritis
    - ii. Acute myelitis
    - iii. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
    - iv. Acute brainstem syndrome
    - v. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions
    - vi. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
  - 3. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

#### IV. CONTINUATION OF THERAPY

Authorization of 12 months for continuation of therapy may be granted when both of the following criteria are met:

Reference number(s)
3968-A

- A. The member demonstrates a positive response to therapy (e.g., reduction in number of relapses).
- B. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

**V. REFERENCES**

- 1. Uplizna [package insert]. Baithersburg, MD: Viela Bio, Inc.; July 2021.
- 2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015; 85:177-189.