

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.; December 2020.
- 2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015; 85:177-189.