SmartHealth Ascension

Inebilizumab-Cdon

(Uplinza®) J1823 (1mg)

Covered with prior authorization

Uplinza® (Inebilizumab-Cdon) may be authorized when the following criteria are met:

- Individual is 18 years of age or older; **AND**
- Individual has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); **AND**
- Documentation is provided that NMOSD is seropositive as confirmed by the presence of anti-aquaporin-4 (AQP4) antibodies.

AND

- Documentation is provided that individual has a history of at least 1 acute attack or relapse in the last 12 months prior to initiation of therapy; **OR**
- Documentation is provided that the individual has a history of at least 2 acute attacks or relapses in the last 24 months prior to initiation of therapy.

Exclusion criteria:

Requests may not be approved for the following:

- Individual is using in combination with rituximab, eculizumab, or satralizumab.
- Individual has active hepatitis B (HBV) infection.
- Individual has active or untreated latent tuberculosis.
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria

Uplinza® (Inebilizumab-Cdon) is considered medically necessary for continued use when initial criteria are met and there is documentation of positive clinical response.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Uplinza® (Inebilizumab-Cdon) is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

References:

1. Cree BAC, Bennett JL, Kim HJ, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): a double-blind, randomised placebo-controlled phase 2/3 trial. Lancet. 2019 Oct 12;394(10206):1352-1363. doi: 10.1016/S0140- 6736(19)31817-3. Epub 2019 Sep 5.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022.
4. Uplinza [Prescribing Information]. Deerfield, IL: Horizon Therapeutics; 2022.

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.