

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Uplizna (inebilizumab-cdon)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Uplizna 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. Neuromyelitis optica spectrum disorder (NMOSD) is a rare, autoimmune disease of the central nervous system that primarily attacks the optic nerves and spinal cord leading to blindness and paralysis.

Uplizna (inebilizumab-cdon) will be considered for coverage when the following criteria are met:

Neuromyelitis Optica Spectrum Disorder (NMOSD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of NMOSD and is seropositive for aquaporin-4 (AQP4) IgG antibodies; AND
4. Member has had 1 or more relapses within the past year; AND
5. Member has tried and failed at least one of the following for 6 months or longer: azathioprine, mycophenolate, rituximab (requires prior auth); AND
6. Member has tested negative for hepatitis B and tuberculosis within the past year or there is attestation they will be tested before starting treatment.
7. **Dosage allowed/Quantity limit:** 300mg IV infusion followed two weeks later by a second 300 mg infusion. Subsequently, (starting 6 months from the first infusion): 300 mg every 6 months. QL: 3 vials every 6 months (maintenance)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document disease stabilization, symptom improvement, and/or reduced frequency of relapses compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Uplizna (inebilizumab-cdon) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/02/2020	New policy for Uplizna created.
07/17/2023	Transferred to new template. Corrected QL.

References:

- 2021 Georgia Code Title 33 – Insurance Chapter 20A - Managed Health Care Plans Article 2 - Patient's Right to Independent Review § 33-20A-31 Definitions. Justia US Law. Accessed April 25, 2023. <https://law.justia.com/codes/georgia/2021/title-33/chapter-20a/article-2/section-33-20a-31/>.
- Uplizna [package insert]. Horizon Therapeutics; 2021.
- Kessler RA, Mealy MA, Levy M. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. *Curr Treat Options Neurol.* 2016;18(1):2. doi:10.1007/s11940-015-0387-9
- Weinshenker B. Neuromyelitis Optica Spectrum Disorder. NORD (National Organization for Rare Disorders). <https://rarediseases.org/rare-diseases/neuromyelitis-optica/>. Published August 25, 2020. Accessed October 2, 2020.
- Mealy MA, Wingerchuk DM, Palace J, Greenberg BM, Levy M. Comparison of relapse and treatment failure rates among patients with neuromyelitis optica: multicenter study of treatment efficacy. *JAMA Neurol.* 2014;71(3):324-330. doi:10.1001/jamaneurol.2013.5699
- IPD Analytics. Accessed October 2, 2020.
- 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;394(10206):1352-1363. doi:10.1016/S0140-6736(19)31817-3

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Revised date: 07/17/2023