CareSource Rxinnovations

PHARMACY POLICY STATEMENT
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 rituximab for at least 6 months (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.
04/22/2024	Removed azathioprine, mycophenolate trial options (rituximab more effective per guidelines).

References:

1. 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/.
2. Uplizna [package insert]. Horizon Therapeutics; 2021.
3. 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
4. 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.
5. 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
6. IPD Analytics. Accessed October 2, 2020.
7. 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: 04/22/2024