

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Uplizna (inebilizumab-cdon)
BILLING CODE	J1823
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT—1 vial every 6 months (maintenance)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Uplizna (inebilizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of NMOSD and is seropositive for aquaporin-4 (AQP4) IgG antibodies (documentation required); 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^{2,4,5} (requires prior auth); AND
6. Member has tested negative for hepatitis B and tuberculosis within the past year; AND
7. **Dosage allowed:** 300mg IV infusion on days 1 and 15 followed by 300mg IV infusion every 6 months.

If member meets all the requirements listed above, 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.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Uplizna (inebilizumab) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/02/2020	New policy for Uplizna created.

References:

1. Uplizna (inebilizumab-cdon) [package insert]. Gaithersburg, MD: Viela Bio Inc.; 2020.

2. 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
3. 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
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.

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