CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

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 and the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.
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.
Immunoglobulin G4-related disease (IgG4-RD) is a multi-organ inflammatory disease characterized by high levels of IgG4 and tumor-like masses. It most commonly affects the pancreas, kidneys, orbital structures, salivary glands, and retroperitoneum.

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.

Immunoglobulin G4-related disease (IgG4-RD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist, immunologist, endocrinologist, hepatologist or nephrologist; AND
3. Member has a diagnosis of IgG4-RD with involvement of at least **TWO** organ systems; AND
4. Member is experiencing or has recently experienced a flare requiring initiation or continuation of glucocorticoids; AND
5. Member is refractory to glucocorticoids (including glucocorticoid-dependent patients who cannot reduce dose without flare); 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:** 300 mg 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 12 months.

For **reauthorization:**

1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares and/or decreased steroid use, etc.

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).
05/15/2025	Updated references. Added Immunoglobulin G4-related disease diagnosis.

References:

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2. Uplizna [package insert]. Horizon Therapeutics; 2025.
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. 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

7. Stone JH, Khosroshahi A, Zhang W, et al. Inebilizumab for Treatment of IgG4-Related Disease. *N Engl J Med.* 2025;392(12):1168-1177. doi:10.1056/NEJMoa2409712
8. Wallace ZS, Katz G, Hernandez-Barco YG, Baker MC. Current and future advances in practice: IgG4-related disease. *Rheumatol Adv Pract.* 2024;8(2):rkae020. Published 2024 Apr 10. doi:10.1093/rap/rkae020
9. Wallace ZS, Naden RP, Chari S, et al. The 2019 American College of Rheumatology/European League Against Rheumatism classification criteria for IgG4-related disease. *Ann Rheum Dis.* 2020;79(1):77-87. doi:10.1136/annrheumdis-2019-216561

Effective date: 10/01/2025
Revised date: 05/15/2025