Uplizna® (inebilizumab-cdon)
(Intravenous)

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I. Length of Authorization

Initial coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 300 billable units on days 1 and 15 and then 300 billable units every 6 months thereafter

III. Initial Approval Criteria [1,2,9]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed to be negative for active HBV; **AND**
- Patient has had baseline serum immunoglobulins measured prior to the start of therapy; **AND**
- Patient does not have an underlying immunodeficiency disorder (e.g., acquired/congenital immunodeficiency, HIV, etc.); **AND**

Universal Criteria [1,2,9]

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Live or live-attenuated vaccinations will not be administered within the 4-weeks prior to the start of therapy and will not be administered concurrently while on therapy; **AND**
- Will not be used in combination with other immunomodulatory biologic therapies or other therapies which can result in prolonged additive immunosuppression (*excluding corticosteroids used as premedication, rescue therapy, or flare treatment*); **AND**

Neuromyelitis Optica Spectrum Disorder (NMOSD) † Φ [1,2,4,5]

- Patient has a confirmed diagnosis based on the following:

- Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
- Patient has at least one core clinical characteristic **§** *(Note: some core clinical characteristics require both clinical and typical MRI findings)*; **AND**
- Alternative diagnoses have been excluded [e.g., myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD), multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.]; **AND**

- Patient has a history of one or more relapses that required rescue therapy within the prior year OR two or more relapses that required rescue therapy within the prior 2 years; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 7.5; **AND**
- Patient has not received intravenous immunoglobulin (IVIG) within one month prior to the start of therapy

§ Core Clinical Characteristics of NMOSD [5]
▪ Acute optic neuritis ▪ Acute myelitis ▪ Area postrema syndrome (APS): episode of otherwise unexplained hiccups and/or nausea and vomiting (lasting for at least 48 hours or with MRI evidence of a dorsal brainstem lesion) ▪ Acute brainstem syndrome other than APS ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesion on MRI **¥** ▪ Acute cerebral syndrome with NMOSD-typical brain lesion on MRI **ψ**
¥ Diencephalic syndrome: Periependymal lesion (3rd ventricle) OR hypothalamic/thalamic lesion **ψ** Cerebral syndrome: Extensive periependymal lesion (lateral ventricle; often with Gd) OR long (> 1⁄2 length), diffuse, heterogeneous or edematous corpus callosum lesion OR long corticospinal tract lesion (unilateral or bilateral, contiguously involving internal capsule and cerebral peduncle) OR large, confluent (unilateral or bilateral) subcortical or deep white matter lesion

Immunoglobulin G4-Related Disease (IgG4-RD) † [1,7-10]

- Patient has a confirmed diagnosis of IgG4-RD (e.g., physical exam findings, imaging results, laboratory tests, pathological findings in involved organ/sites, etc.); **AND**
- Other conditions that mimic IgG4-RD have been ruled out (e.g., malignancy, infection, other autoimmune disorders, etc.); **AND**
- Patient is experiencing (or recently experienced) an IgG4-RD flare that required corticosteroid treatment; **AND**
  - Patient has disease that is refractory to corticosteroids; **OR**
  - Patient has a contraindication or intolerance to corticosteroid treatment; **AND**
- Patient is at high risk of recurrent disease flares based on a history of disease in ≥2 organs/sites; **AND**
- At least one of the following organs are affected:
  - Pancreas, bile ducts/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, and/or thyroid gland

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1,2,7,9]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infusion related reactions (e.g., headache, nausea, somnolence, dyspnea, fever, myalgia, rash, etc.), serious infections including progressive multifocal leukoencephalopathy (PML), hypogammaglobulinemia necessitating IVIG treatment or leading to recurrent infections, etc.; **AND**

Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Disease response as indicated by stabilization/improvement in one or more of the following:
    - Neurologic symptoms as evidenced by a decrease in acute relapses, improvement in stability, or improvement in EDSS
    - Reduced hospitalizations
    - Reduction/discontinuation in plasma exchange treatments

Immunoglobulin G4-Related Disease (IgG4-RD)

- Disease response as indicated by one or more of the following:
    - Reduction in corticosteroid requirement for IgG4-RD flare treatment from baseline
    - Reduction in IgG4-RD flares from baseline
    - Stabilization/improvement in symptoms, physical exam findings, imaging results, laboratory tests, and/or pathological findings in IgG4-RD involved organ/sites compared to baseline

V. Dosage/Administration [1]

Indication	Dose
All Indications	Uplizna is administered as an intravenous infusion, as follows: • Initial dose: 300 mg IV infusion followed 2 weeks later by a second 300 mg IV infusion. • Subsequent doses *(starting 6 months from the first infusion)*: single 300 mg IV infusion every 6 months.
Administer Uplizna under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage potential severe reactions such as serious infusion reactions.	

VI. Billing Code/Availability Information

HCPCS Code:

- J1823 – Injection, inebilizumab-cdon, 1 mg; 1 billable unit = 1 mg

NDC:

- Uplizna 100 mg/10 mL single-dose vials for injection: 75987-0150-xx

VII. References

1. Uplizna [package insert]. Dublin, Ireland; Horizon Therapeutics Ireland DAC; April 2025. Accessed April 2025.
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10. Nambiar S, Oliver TI. IgG4-Related Disease. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK499825/

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G36.0	Neuromyelitis optica [Devic]
D89.84	IgG4-related disease

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC