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

A. Quantity Limit (max daily dose) [NDC Unit]:

Loading Doses: 3 vials on days 1, 15

Maintenance Dose: 3 vials every 6 months

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

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

III. Initial Approval Criteria [1,2]

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; **AND**
- Patient serum immunoglobulin baseline measured prior to the start of therapy; **AND**
- Patient does not have an underlying immunodeficiency disorder (i.e., acquired/congenital primary immunodeficiency, HIV, etc.); **AND**
- Patient has not received any vaccinations in the 4-weeks prior to the start of therapy; **AND**

Universal Criteria [1,2]

- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**

- Will not be administered concurrently with live or live-attenuated vaccines; **AND**
- Patients is not concomitantly receiving therapy with other immunosuppressant type drugs (i.e., alemtuzumab, natalizumab, cyclosporin, methotrexate, mitoxantrone, cyclophosphamide, tocilizumab, maintenance corticosteroids (not including pre-medications or rescue therapy), etc.) or other immunosuppressant procedures (i.e., total lymphoid irradiation, bone marrow transplant, etc.); **AND**
- Will not be used in combination with a complement-inhibitor (i.e., eculizumab, ravulizumab) or anti-CD20-directed antibody (i.e., rituximab) or IL-6 inhibitor (e.g., satralizumab) therapies; **AND**

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

- 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 §; **AND**
  - Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); **AND**
- Patient has a history of one or more relapses that required rescue therapy within the year prior to screening, or 2 or more relapses that required rescue therapy in 2 years prior to screening; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 7.5 (i.e., inability to take more than a few steps; restricted to wheelchair and may need aid in transferring; can wheel self but cannot carry on in standard wheelchair for a full day and may require a motorized wheelchair)

§ Core Clinical Characteristics of NMOSD [15]
▪ Optic neuritis ▪ Acute myelitis ▪ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting ▪ Acute brainstem syndrome ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions ▪ Symptomatic cerebral syndrome with NMOSD-typical brain lesions

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

IV. Renewal Criteria [1,2]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet 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 the following: serious or life-threatening infusion related reactions, serious infections including PML, hypogammaglobulinemia necessitation IVIG or leading to recurrent infections, etc.; **AND**
- Disease response as indicated by stabilization/improvement in any of the following: neurologic symptoms as evidenced by a decrease in acute relapses, stability or improvement in EDSS, reduced hospitalizations, and/or reduction in plasma exchange treatments

V. Dosage/Administration

Indication	Dose
Neuromyelitis Optica Spectrum Disorder (NMOSD)	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.
– *Uplizna must be diluted prior to administration. Prior to the start of the intravenous infusion, the prepared infusion solution should be at room temperature.* – *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.* – *Administer the prepared solution intravenously via an infusion pump at an increasing rate to completion, approximately 90 minutes, according to the schedule in the PI.* – *Administer through an intravenous line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter.*	

VI. Billing Code/Availability Information

HCPCS code:

J3590 – Unclassified biologics
C9399 – Unclassified drugs or biologicals
J1823 – Injection, inebilizumab-cdon, 1 mg; 1 billable unit = 1 mg *(Effective 1/1/21)*

NDC:

Uplizna 100 mg/10 mL single-use vials for injection: 72677-0551-xx

VII. References

1. Uplizna [package insert]. Gaithersburg, MD; Viela Bio, Inc; June 2020. Accessed September 2020.
2. Cree BAC, Bennett JL, Kim HJ, et al; N-MOmentum study investigators. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): a double-blind, randomised placebo-controlled phase 2/3 trial. Lancet. 2019 Oct 12;394(10206):1352-1363. doi: 10.1016/S0140-6736(19)31817-3. Epub 2019 Sep 5.

3. Trebst C, Jarius S, Berthele A, et al. Update on the diagnosis and treatment of neuromyelitis optica: recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol 2014; 261:1.
4. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015 Jul;85(2):177-89. Epub 2015 Jun 19.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G36.0	Neuromyelitis optica [Devic]

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

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 Determination (NCD), Local Coverage Article (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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