Uplizna® (inebilizumab-cdon)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) 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

Target Agent(s) will be approved when ALL of the following are met:

- ONE of the following:
  - The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) AND ALL of the following:
    - The patient is anti-aquaporin-4 (AQP4) antibody positive (lab test required); **AND**
    - The diagnosis was confirmed by at least ONE of the following:
      - Optic neuritis; **OR**
      - Acute myelitis; **OR**
      - Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting); **OR**
      - Acute brainstem syndrome; **OR**
      - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; **OR**
      - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; **AND**

- The patient has had at least 1 discrete clinical attack of CNS symptoms; **AND**
- Alternative diagnoses (e.g., multiple sclerosis, ischemic optic neuropathy) have been ruled out; **AND**
- The patient will NOT be using the requested agent in combination with Enspryng (satralizumab-mwge), Rituximab, Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), or Ultomiris (ravulizumab-cwvz); **OR**

– The patient has a diagnosis of Immunoglobulin G4-Related Disease (IgG4-RD) AND ALL of the following:

- Patient is at high risk of recurrent disease flares based on a history of disease in greater than or equal to 2 organs/sites; **AND**
- Alternative diagnoses (e.g., malignancy, infection, other autoimmune disorders) have been ruled out; **AND**
- The patient has ONE of the following:
  - Tried and had an inadequate response to ONE corticosteroid used in the treatment of IgG4-RD; **OR**
  - An intolerance or hypersensitivity to ONE corticosteroid used in the treatment of IgG4-RD; **OR**
  - An FDA labeled contraindication to ALL corticosteroids; **OR**

– The patient has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following:

- ONE of the following: (medical records required)
  - The patient has a positive serological test for anti-AChR antibodies; **OR**
  - The patient has a positive serological test for anti-MuSK antibodies; **AND**
- The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
- The patient has a MG-Activities of Daily Living total score of greater than or equal to 6; **AND**
- ONE of the following:
  - The patient's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued; **OR**
  - Discontinuation of the offending agent is NOT clinically appropriate; **AND**
- ONE of the following:
  - The patient has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids,

azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**

- The patient has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
- The patient has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
- The patient required chronic intravenous immunoglobulin (IVIG); **OR**
- The patient required chronic plasmapheresis/plasma exchange; **AND**

- The patient will NOT be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), Imaavy (nipocalimab-aahu), or Rystiggo (rozanolixizumab-noli); **OR**

– The patient has another FDA labeled indication for the requested agent and route of administration; **AND**

- If the patient has an FDA labeled indication, then ONE of the following:
  – The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
  – There is support for using the requested agent for the patient's age for the requested indication; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, immunologist, allergist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The prescriber has screened the patient for hepatitis B viral (HBV) infection AND BOTH of the following:
  – The patient does NOT have an active HBV infection; **AND**
  – If the patient has had a previous HBV infection or is a carrier for HBV infection the prescriber has consulted with a gastroenterologist or a hepatologist before initiating and during treatment with the requested agent; **AND**
- The patient has had testing for quantitative serum immunoglobulins AND ONE of the following:
  – The patient has normal serum immunoglobulin levels; **OR**
  – The patient has low serum immunoglobulin levels AND the prescriber has consulted with an immunologist before initiating treatment with the requested agent; **AND**

- The patient does NOT have active or untreated tuberculosis; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The patient has been previously approved for the requested agent through the plan's Medical Drug Review process (Note: patients not previously approved for the requested agent will require initial evaluation review); **AND**
- The patient has had clinical benefit with the requested agent; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, immunologist, allergist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- BOTH of the following:
  - The patient does NOT have active hepatitis B infection; **AND**
  - If the patient has had a previous HBV infection or is a carrier for HBV infection the prescriber continues to consult with a gastroenterologist or a hepatologist during treatment with the requested agent; **AND**
- The patient does NOT have active or untreated latent tuberculosis; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- If the patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD), then the patient will NOT be using the requested agent in combination with Enspryng (satralizumab-mwge), Rituximab, Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), or Ultomiris (ravulizumab-cwvz); **AND**
- If the patient has a diagnosis of generalized Myasthenia Gravis (gMG), then the patient will NOT be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), Imaavy (nipocalimab-aahu), or Rystiggo (rozanolixizumab-noli); **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

V. Dosage/Administration

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

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA

Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D89.84	IgG4-related disease
G36.0	Neuromyelitis optica [Devic]
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
15	KY, OH	CGS Administrators, LLC