Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Inebilizumab-cdon (Uplizna®)	MP-RX-FP-98-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Inebilizumab-cdon (Uplizna®) , a drug approved by the Food and Drug Administration (FDA) for the treatment of neuromyelitis optica spectrum disorder (NMSOD).

Background Information

This document addresses the use of Uplizna (inebilizumab-cdon), a humanized monoclonal antibody directed against CD19 receptors on B cells. Uplizna treats neuromyelitis optica spectrum disorder (NMSOD) by depleting antibody-secreting plasma cells.

NMOSD is a severe autoimmune disease of the central nervous system caused by immune-mediated demyelination and axonal damage predominantly targeting optic nerves and spinal cord. This damage is triggered by antibodies against aquaporin-4 (AQP4), which are considered biomarkers for NMOSD. The disease is characterized by clusters of attacks of optic neuritis or transverse myelitis with partial recovery between attacks. Progressive visual impairment and paralysis may be caused by repeated attacks, so long-term prevention therapy should be offered to all patients. Treatment may include off label immunosuppressive therapies including rituximab, azathioprine, and mycophenolate. Three agents are FDA approved for NMOSD: Uplizna, Enspryng and Soliris. Uplizna has a unique mechanism of action by causing antibody-dependent cellular cytolysis of B-cells. It is given via intravenous infusion once every 6 months.

Uplizna can increase the risk of infection, as it is an immunosuppressant. It is contraindicated in those with active hepatitis B (HBV) infection and those with active or untreated latent tuberculosis (TB). Prior to initiation of therapy, all individuals should receive HBV screening, TB screening, and quantitative serum immunoglobulin testing. Individuals should also receive all immunizations according to guidelines prior to initiating therapy.

Approved Indications

A. Neuromyelitis Optica Spectrum Disorder (NMSOD) in adults' patients who are anti-aquaporin-4 (AQP4) antibody positive.

Other Uses

N/A

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J1823	Injection, inebilizumab-cdon, 1 mg [Uplizna]

ICD-10	Description
G36.0-G36.9	Neuromyelitis optica [Devic]

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Inebilizumab-cdon (Uplizna®)

A. Criteria For Initial Approval

Requests for initiation of therapy with Uplizna (inebilizumab-cdon) may be approved if the following criteria are met:

i. Individual is 18 years of age or older; **AND**
ii. Individual has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); **AND**
iii. Documentation is provided that NMOSD is seropositive as confirmed by the presence of anti-aquaporin-4 (AQP4) antibodies; **AND**
iv. Documentation is provided that individual has a history of at least 1 acute attack or relapse in the last 12 months prior to initiation of therapy;

OR

v. Documentation is provided that individual has a history of at least 2 acute attacks or relapses in the last 24 months prior to initiation of therapy (Cree 2019); **AND**
vi. If initiating therapy, individual has been evaluated and tested for Hepatitis B Virus (HBV) infection and latent tuberculosis infection

B. Criteria For Continuation of Therapy

Requests for continued use of Uplizna (inebilizumab-cdon) in NMOSD may be approved if the following criteria are met:

i. Documentation is provided that individual has experienced a clinical response (for example, a reduction in the frequency of relapse).

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. All other indication not included above;

OR

ii. Individual is using in combination with rituximab, eculizumab, or satralizumab;

OR

iii. Individual has active hepatitis B (HBV) infection [repeat testing not required for continuation of therapy];

OR

iv. Individual has active or untreated latent tuberculosis [repeat testing not required for continuation of therapy];

OR

v. When the above criteria are not met and for all other indications.

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D. Authorization Duration

i. Initial Approval Duration: 1 year

ii. Reauthorization Approval Duration: 1 year

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Limits or Restrictions

A. Therapeutic Alternatives
The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Uplizna (inebilizumab-cdon) 100 mg/10 mL vial	3 vials (300 mg) every 6 months
Exceptions	
May approve 3 (three) additional vials in the first two weeks of treatment. The total allowed quantity for initiation of therapy is 300 mg once followed by 300 mg two weeks later.	

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 30, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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 Oct 12;394(10206):1352-1363. doi: 10.1016/S0140- 6736(19)31817-3. Epub 2019 Sep 5.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Choose an item.		Click or tap to enter a date.	Click or tap to enter a date.
Annual Review 11/15/2024	Update infectious disease testing requirements per label, wording and formatting updates. Coding Reviewed: No changes.	3/14/2025	4/2/2025
Policy Inception 11/1/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023