Clinical Criteria

Subject:	Uplizna (inebilizumab-cdon)		
Document #:	ING-CC-0170	**Publish Date:**	12/20/2021
Status:	Reviewed	**Last Review Date:**	11/19/2021

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Overview

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.

Clinical Criteria

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.

Uplizna (inebilizumab-cdon)

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).

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).

Requests for Uplizna (inebilizumab-cdon) may not be approved if the above criteria are not met and for all other indications.

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; **OR**
IV. Individual has active or untreated latent tuberculosis.

Initial and Continuation Approval Duration: 1 year

Quantity Limits

Uplizna (inebilizumab-cdon) Quantity Limit

Drug	Limit
Uplizna (inebilizumab-cdon) 100 mg/10 mL vial	3 vials (300 mg) every 6 months
Override Criteria	
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.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1823	Injection, inebilizumab-cdon, 1 mg [Uplinza]

ICD-10 Diagnosis

G36.0-G36.9	Neuromyelitis optica [Devic]

Document History

Revised: 11/19/2021
Document History:

- 11/19/2021 – Annual Review: Clarify approval durations; update may not approve criteria to include combination use with other NMOSD agents; clarify relapse/acute attack requirement. Coding Reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 11/20/2020 – Annual Review: No changes. Coding reviewed: No changes. Effective 1/1/2021 Added J1823, Deleted 12/31/2020, J3590, C9399. Added ICD-10-CM G36.0-G36.9.
- 08/21/2020 – Annual Review: Add new clinical criteria document for Uplizna (inebilizumab-cdon). Coding Reviewed: Added HCPCS: J3590, C9399, ICD-10-CM:All diagnosis pend

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; 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.