

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

Uplizna (inebilizumab-cdon)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Uplizna (inebilizumab-cdon) 100 mg/10 mL vial	3 vials (300 mg) every 6 months*

*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.

APPROVAL CRITERIA

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. NMOSD is seropositive as confirmed by the presence of anti- aquaporin-4 (AQP4) antibodies;

AND

- IV. Individual has a history of at least 1 relapse in the last 12 months prior to initiation of therapy; **OR**
- V. Individual has a history of at least 2 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. 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.

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

- I. All other indication not included above; **OR**
- II. Individual has active hepatitis B (HBV) infection; **OR**
- III. Individual has active or untreated latent tuberculosis.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: July 7, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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 policies may take precedence over the application of this clinical criteria.

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