

Uplizna™ (inebilizumab-cdon) injection

When requesting Uplizna™ (inebilizumab-cdon) injection, the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 antibody positive.

Coverage Guidelines

Neuromyelitis optica spectrum disorder (NMOSD)

The individual must meet **all** of the following criteria for initial authorization:

- Is 18 years of age or older;
- Diagnosis has been confirmed by blood serum test for anti-aquaporin-4 antibody positive neuromyelitis optica spectrum disorder;
- Has previously tried Soliris or Enspryng, OR
- Is currently receiving or has previously tried two of the following systemic therapies: azathioprine, corticosteroid, mycophenolate mofetil, rituximab, AND
- Has had a history of at least one relapse in the last 12 months or two relapses in the last 2 years
- Uplizna is prescribed by or in consultation with a neurologist.

The individual must meet **all** of the following criteria for re-authorization:

- Is 18 years of age or older;
- Diagnosis has been confirmed by blood serum test for anti-aquaporin-4 antibody positive neuromyelitis optica spectrum disorder;
- Has had clinical benefit (examples: reduction in relapse rate, reduction in symptoms [e.g. pain, fatigue, motor function], slowing progression in symptoms).
- Uplizna is prescribed by or in consultation with a neurologist.

Approval duration: 12 months

Dosing Recommendations

Approve 300 mg by intravenous infusion once every 2 weeks for 2 doses, then 300 mg by intravenous infusion once every 6 months thereafter, starting 6 months from the first infusion.

References

1. Uplizna™ injection [prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc; July 2021.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Available at: <https://rarediseases.org/rare-diseases/neuromyelitis-optica/>. Accessed September 26, 2021.
3. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015;85(2):177-189.
4. Soliris® injection [prescribing information]. Boston, MA: Alexion Pharmaceuticals; November 2020.
5. Bradshaw M and Kimbrough D. Neuromyelitis Optica Spectrum Disorders. *Practical Neurology*. 2019;76-84.
6. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. https://wearesna.org/wp-content/uploads/2018/06/About_NMOSD_2018.pdf. Accessed September 26, 2021.
7. Enspryng® injection [prescribing information]. South San Francisco, CA: Genentech, Inc.; August 2020.