

Uplizna™ (inebilizumab-cdon) injection

When requesting Uplizna™ (inebilizumab-cdon) injection, the individual requiring treatment must be diagnosed with the following 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;
- 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

The recommended dose is 300 mg administered by intravenous infusion once every 2 weeks for 2 doses, then 300 mg administered by intravenous infusion once every 6 months thereafter, starting 6 months from the first infusion.

References

1. Uplizna® intravenous infusion [prescribing information]. Deerfield, IL: Horizon Therapeutics; July 2021.
2. National Organization for Rare Disorders. Neuromyelitis Optica Spectrum Disorder. Last updated July 27, 2022. Available at: <https://rarediseases.org/rare-diseases/neuromyelitis-optica/>. Accessed September 22, 2024.
3. Chan KH, Lee CY. Treatment of neuromyelitis optica spectrum disorders. *Int J Mol Sci.* 2021;22(16):8638.
4. Kümpefel T, Gighuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. *J Neurol.* 2024;271:141-176.