

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;
- Meets one of the following:
 - Has previously tried Soliris or Enspryng
 - Is currently receiving or has previously tried two of the following systemic therapies: azathioprine, corticosteroid, mycophenolate mofetil, rituximab
- 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

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 October 4, 2023.
3. Chan KH, Lee CY. Treatment of neuromyelitis optica spectrum disorders. *Int J Mol Sci*. 2021;22(16):8638.
4. Enspryng® subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; March 2022.
5. Soliris® intravenous infusion [prescribing information]. Boston, MA: Alexion; November 2020.