

Uplizna® (inebilizumab-cdon) Injection

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

FDA-approved Indications

Uplizna is a CD19-directed cytolytic antibody indicated for:

- The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
- The treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.

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 from the use of Uplizna (e.g., 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.

Immunoglobulin G4-related Disease

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

- Is 18 years of age or older;
- Has had a history of involvement of at least one organ (e.g., aorta, pancreas, kidneys, bile ducts, lacrimal glands, major salivary glands, thyroid gland);
- Meets one of the following:
 - o Has received or is currently receiving a systemic corticosteroid; OR

- o Has had inadequate efficacy, a contraindication, or significant intolerance to a systemic corticosteroid;
- Uplizna is prescribed by or in consultation with one of the following specialists: endocrinologist, gastroenterologist, immunologist, nephrologist, neurologist, pulmonologist, rheumatologist, or a physician who specializes in treating immune-mediated disorders.

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

- Is 18 years of age or older;
- Has had clinical benefit from the use of Uplizna (e.g., reduction in the corticosteroid dose, reduction in the number of disease flares, increase in the duration of flare-free period, or absence of disease activity);
- Uplizna is prescribed by or in consultation with one of the following specialists: endocrinologist, gastroenterologist, immunologist, nephrologist, neurologist, pulmonologist, rheumatologist, or a physician who specializes in treating immune-mediated disorders.

Approval duration (Initial and Renewal): 12 months

Dosing Recommendation

Uplizna is administered as an intravenous infusion. The recommended dosage is:

- Initial dose: 300 mg intravenous infusion followed 2 weeks later by a second 300 mg intravenous infusion.
- Subsequent doses (starting 6 months from the first infusion): single 300 mg intravenous infusion every 6 months.

References

1. Uplizna® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen and Dublin, Ireland: Horizon; April 2025.
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3. Chan KH, Lee CY. Treatment of neuromyelitis optica spectrum disorders. *Int J Mol Sci.* 2021;22(16):8638.
4. Kümpfel T, Gíglhuber 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.
5. Nambiar S, Oliver TI. IgG4-related disease. Available at: [IgG4-Related Disease - StatPearls - NCBI Bookshelf](#). Accessed on May 9, 2025.
6. Uplizna AMCP Dossier – Amgen. Version 1 (April 2025). Received on May 16, 2025.
7. Wallace ZS, Naden RP, Chari S, et al. The 2019 American College of Rheumatology/European League Against Rheumatism classification criteria for IgG4-related disease. *Arthritis & Rheumatol.* 2020;72:7-19.
8. Stone JH, Khosroshahi A, Zhang W, et al. Inebilizumab for treatment of IgG4-related disease. *N Engl J Med.* 2025;392: 1168-1177.
9. Umehara H, Okazaki K, Kawa S. The 2020 revised comprehensive diagnostic (RCD) criteria for IgG4-RD. *Mod Rheumatol.* 2021 May;31(3):529-533.