

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.
- Immunoglobulin G4-related disease (IgG4-RD) in adult patients.
- Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive.

Coverage Guidelines

Generalized Myasthenia Gravis (gMG)

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

- Is 18 years of age or older;
- Has confirmed anti-acetylcholine receptor antibody-positive OR anti-muscle-specific tyrosine kinase antibody-positive generalized myasthenia gravis;
- Has Myasthenia Gravis Foundation of America Class II to IV;
- Has Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of 6 or higher;
- Has received or is currently receiving pyridostigmine unless patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine;
- Has evidence of unresolved symptoms of generalized myasthenia gravis (e.g., difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity [e.g., double vision, speech, impairment of mobility]);
- 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;
- Is continuing to receive benefit from Uplizna therapy (e.g., reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, or respiratory function);
- Uplizna is prescribed by or in consultation with a neurologist.

Approval duration (initial): 6 months
Approval duration (renewal): 12 months

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.

Approval duration (Initial and Renewal): 12 months

Immunoglobulin G4-related Disease (IgG4-RD)

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);
- The diagnosis of IgG4-RD is confirmed by at least one of the following:
 - o A biopsy of at least one involved organ and immunostaining confirms presence of IgG-positive cells; OR
 - o Imaging of at least one organ or area of the body (e.g., computed tomography, magnetic resonance imaging, positron emission tomography); OR
 - o Has elevated IgG4 levels and histopathologic features of IgG4-RD (e.g., dense lymphocytic infiltrate, dense lymphocytic infiltrate and obliterative phlebitis, dense lymphocytic infiltrate, or storiform fibrosis with or without obliterative phlebitis);
- 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;

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- 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

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