

inebilizumab-cdon (Uplizna)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS

Mechanism of Action: CD19-directed cytolytic antibody

HCPCS:

J1823:Injection, inebilizumab-cdon, 1 mg

How Supplied:

100 mg/10 mL (10 mg/mL) solution in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Generalized Myasthenia Gravis (gMG)
- Immunoglobulin G4-related Disease (IgG4-RD)
- Neuromyelitis Optica Spectrum Disorder (NMOSD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct) may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is starting new therapy with this drug (allowed for 3 doses). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on this drug after being off therapy for at least 6 months (allowed for 3 doses). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
 - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
 - b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
 - c. Patient is clinically unstable based on documentation submitted.
 - d. Patient is physically or cognitively unstable based on documentation submitted

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Generalized Myasthenia Gravis (gMG)

Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with a neurologist
2. Meets one of the following:
 - a. Patient has a positive serological test for Anti-AChR, and BOTH of the following:
 - i. Patient is on at least one treatment for gMG (e.g. acetylcholinesterase inhibitors, corticosteroids, or non-steroid immunosuppressive therapies)
 - ii. Patient had an inadequate response, intolerable side effect, or contraindication to one preferred product (e.g. Vyvgart, Vyvgart Hytrulo, or Epysqli)
 - b. Patient has a positive serological test for Anti-MuSK
3. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score greater than or equal to 3

Reauthorization

1. Patient's continued response to therapy as shown by one of the following:
 - a. Improvement of at least 2 points (reduction in score) in MG-ADL score
 - b. Reduction in signs of symptoms of myasthenia gravis

Covered Doses:

Initial: Up to 300 mg given intravenously for one dose, followed by 300 mg two weeks later. A third dose of 300 mg is given 6 months from the first infusion.

Reauthorization: Up to 300 mg given intravenously every 6 months

Coverage Period:

Initial: For the first 3 doses

Reauthorization: Yearly

Immunoglobulin G4-related Disease (IgG4-RD)

Meets medical necessity if all the following are met:

Initial:

1. Prescribed by or in consultation with a rheumatologist or immunologist
2. History of organ involvement (e.g., pancreas, bile ducts/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, or thyroid gland (Riedel's thyroiditis))
3. Currently experiencing or recently experienced an IgG4-RD flare that required glucocorticoid treatment
4. Dose does not exceed the FDA-approved maximum

Reauthorization:

1. Patient is responding to therapy
2. Dose does not exceed the FDA-approved maximum

Covered Doses:

Initial: Up to 300 mg given intravenously for one dose, followed by 300 mg two weeks later. A third dose of 300 mg is given 6 months from the first infusion.

Reauthorization: Up to 300 mg given intravenously every 6 months

Coverage Period:

Initial: For the first 3 doses

Reauthorization: Yearly, based on continued response to therapy

Neuromyelitis Optica Spectrum Disorder (NMOSD)

Meets medical necessity if all the following are met:

Initial:

1. Prescribed by or in consultation with by a neurologist
2. Positive for anti-aquaporin-4 (AQP4) antibodies
3. Not being used in combination with another drug therapy for NMOSD (e.g. rituximab, satralizumab)
4. Meets one of the following (a or b):
 - a. Patient has had an inadequate response or intolerance to rituximab
 - b. Patient has not been treated with rituximab AND has a contraindication to Ruxience and Truxima

Reauthorization:

1. Documented reduction in frequency of NMO attacks from baseline
2. Prescribed by or in consultation with a neurologist

3. Not being used in combination with another drug therapy for NMOSD (e.g. rituximab, satralizumab)

Covered Doses:

Initial: Up to 300 mg given intravenously for one dose, followed by 300 mg two weeks later. A third dose of 300 mg is given 6 months from the first infusion.

Reauthorization: Up to 300 mg given intravenously every 6 months

Coverage Period:

Initial: For the first 3 doses

Reauthorization: Yearly

ICD-10:

G36.0

References

1. AHFS®. Available by subscription at <http://www.lexi.com>
2. DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Uplizna (inebilizumab) [prescribing information]. Deerfield, IL: Horizon Therapeutics USA Inc; December 2025.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- Add coverage for generalized myasthenia gravis in adults who are anti-AChR or anti-MuSK antibody-positive (**Rationale:** In December 2025, Uplizna was FDA approved for generalized myasthenia gravis in adult patients who are anti-AChR or anti-MUSK antibody positive)

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*