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)*

- Immunoglobin 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.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****
MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract),** 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.

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

1. **Patient is receiving the first 3 doses of Uplizna or is being re-initiated on Uplizna (allowed for 3 doses) after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event to Uplizna based on documentation submitted.**
3. **Patient continues to experience moderate to severe adverse events to Uplizna based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**
4. **Patient is clinically unstable based on documentation submitted.**
5. **Patient is physically or cognitively unstable based on documentation submitted.**

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

Immunoglobin 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. ***Effective 11/1/2025:*** Prescribed by or in consultation with a neurologist
3. ***Effective 11/1/2025:*** 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; April 2025.

Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- Add coverage for treatment of Immunoglobulin G4-related disease (IgG4-RD) in adults. - ***Rationale:*** In April 2025, the FDA approved Uplizna for the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.
- Clarify use of Uplizna is not to be used in combination with other guideline-supported agents for NMOSD - ***Rationale:*** ensure appropriate use
- Add specialist requirement and management of combination use with other agents used for NMOSD - ***Rationale:*** ensure appropriate use

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