Original Effective Date: 03/01/2016
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Next Review Due By: 07/2026
Policy Number: C20171-A

Uplizna (inebilizumab-cdon)

PRODUCTS AFFECTED

Uplizna (inebilizumab-cdon)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Neuromyelitis optica spectrum disorder (NMOSD), Immunoglobulin G4-related disease (IgG4-RD), Generalized myasthenia gravis (gMG)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
1. Documentation of diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
   AND

2. Documentation diagnosis was confirmed by blood serum test for anti- aquaporin-4 antibody positive (AQP4-IgG) [DOCUMENTATION REQUIRED]
   AND
3. Documentation of at least one core clinical characteristic from among the following: optic neuritis (ON), acute myelitis, acute postrema syndrome (APS, characterized by unexplained hiccups or nausea and vomiting), acute brainstem syndrome, symptomatic narcolepsy, or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, and symptomatic cerebral syndrome with NMOSD-typical brain lesions
   AND
4. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
   AND
5. Member is not concomitantly receiving therapy with other immunosuppressant type drugs (i.e., alemtuzumab, natalizumab, cyclosporine, methotrexate, mitoxantrone, cyclophosphamide, tocilizumab, maintenance corticosteroids [not including pre- medications or rescue therapy, or doses of 20 mg or less a day], etc.)
   AND
6. Member will not be using in combination with complement- inhibitor (i.e., eculizumab, ravulizumab) or anti-CD20-directed antibody (i.e., rituximab) therapies
   AND
7. Documentation of member baseline status [DOCUMENTATION REQUIRED]:
   (a) One or more relapses that required rescue therapy within the previous 12 months OR 2 or more relapses that required rescue therapy within the previous 2 years
   NOTE: Rescue therapies include IV corticosteroids, and/or plasma exchange
   AND
   (b) Documentation that member has a baseline Expanded Disability Status Scale (EDSS) score ≤ 8
   AND
   (c) Documentation of baseline relapse rate and visual acuity

B. IMMUNOGLOBULIN G4-RELATED DISEASE (IgG4-RD):

1. Documented diagnosis of immunoglobulin G4-related disease (IgG4-RD) (See Appendix)
   AND
2. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
   AND
3. Documentation of IgG4-RD affecting 2 or more organs/sites at any time of the disease course (e.g., pancreas, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, thyroid gland, etc.)
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., baseline symptoms and frequency of flares)
   AND
5. Documented inadequate response or contraindication to glucocorticoid therapy
   MOLINA REVIEWER NOTE: Refractory to glucocorticoids is defined as patients who do not experience symptom relief, reduction in mass/organ size, improvement in organ function, or adequate decreases in serum IgG4 concentrations from glucocorticoid alone. This includes patients who are glucocorticoid-dependent (i.e., unable to reduce glucocorticoid dose to <5 mg/day) without causing disease flare or worsening of symptoms.
   AND
6. Member is not concomitantly receiving therapy with other immunosuppressant type drugs (i.e., alemtuzumab, natalizumab, cyclosporine, methotrexate, mitoxantrone, cyclophosphamide, tocilizumab, maintenance corticosteroids [not including pre-medications or rescue therapy, or doses of 20 mg or less a day], etc.) or using in combination with anti-CD20-directed antibody (i.e., rituximab) therapies

C. GENERALIZED MYASTHENIA GRAVIS:
1. Documented diagnosis of generalized myasthenia gravis
   AND
2. Documentation member has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV confirmed by positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab) OR anti-muscle-specific tyrosine kinase (MuSK) antibodies [DOCUMENTATION REQUIRED]
   AND
3. Documentation of member's Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score (or other means for treatment plan efficacy monitoring)
   AND
4. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
   AND
5. Documentation of an inadequate treatment response (2 week trial period), serious side effects, or contraindication to pyridostigmine AND formulary glucocorticoids
   AND
6. Inebilizumab will not be used concurrently with Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab), Vyvgart/Vyvgart Hytrulo (efgartigimod), or Zilbrysq (zilucoplan)

CONTINUATION OF THERAPY:

A. NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Documentation therapy has resulted in clinical improvement or stabilization from baseline or from the previous authorization, including but not limited to frequency of relapse, EDSS, Reduction of hospitalizations, Reduction in plasma exchange treatments or Visual acuity [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., serious infusion reactions, serious systemic infections, etc.)
   AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

B. IMMUNOGLOBULIN G4-RELATED DISEASE (IgG4-RD):
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Documentation of positive clinical response as demonstrated by decreased frequency and/or severity of flares and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., serious infusion reactions, serious systemic infections, etc.)
   AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

C. GENERALIZED MYASTHENIA GRAVIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication

fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND

2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., serious infusion reactions, serious systemic infections, etc.)
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms as evidenced by ONE of the following:
   a. Improvement (reduction in score) from pre-treatment baseline on the Myasthenia Gravis-Specific Activities of Daiy Living (MG-ADL) assessment
   b. Reduction in signs and symptoms of myasthenia gravis
   c. Stabilization, reduction, or discontinuation of doses(s) of baseline immunosuppressive therapy (IST) prior to starting therapy

   AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with a neurologist, immunologist, rheumatologist, immunologist, endocrinologist, nephrologist, hepatologist, or other provider with experience in treating IgG4-RD. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization]

AGE RESTRICTIONS:
18 years of age and older

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

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Uplizna (inebilizumab-cdon). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous infusion

DRUG CLASS:
Monoclonal Antibodies

FDA-APPROVED USES:
Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive and the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients and Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Appendix 1:
The 2019 American College of Rheumatology/European League Against Rheumatism classification criteria for IgG4-related disease
The derivation cohort was used to assess the relative performance of each proposed exclusion and inclusion criterion. The exclusion criteria are not designed to be a "laundry list" of evaluations that must be checked off as negative before a patient can be classified as having IgG4-RD.Rather, they serve as a reminder to the investigator of evaluations that might be appropriate to consider in specific clinical scenarios. Criteria that did not distinguish IgG4-RD cases from mimickers were eliminated, and those that helped distinguish IgG4-RD cases from mimickers were retained. A preliminary score of 20 was identified as the cutoff point at or above which the majority of investigators considered the patient to have IgG4-RD.
Step 1. Entry Criteria: Characteristic* clinical or radiologic involvement of a typical organ (e.g., pancreas, salivary glands, bile ducts, orbits, kidney, lung, aorta, retroperitoneum, pachymeninges, or thyroid gland [Riedel's thyroiditis]) OR pathologic evidence of an inflammatory process accompanied by a lymphoplasmacytic infiltrate of uncertain etiology in one of these same organs.
Step 2. Exclusion criteria: domains and items
If case meets entry criteria and does not meet any exclusion criteria, proceed to step 3.
Step 3. Inclusion criteria: domains and items
Step 4. Total inclusion points: A case meets the classification criteria for IgG4-RD if the entry criteria are met, no exclusion criteria are present, and the total points is ≥20.

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
NMOSD is a rare, relapsing, autoimmune disorder of the brain and spinal cord with optic neuritis and/or myelitis as predominate characteristic symptoms. NMOSD often causes significant, permanent damage to vision and/or spinal cord function causing blindness or impaired mobility.
Patients may experience pain, paralysis, loss of bowel and bladder control, loss of visual acuity, uncontrolled motor functions, and complications can cause death. Soliris® (eculizumab for intravenous use), a complement inhibitor, is the only other FDA-approved medication for treatment of NMOSD in adult patients who are anti-aquaporin-4 antibody positive. For acute attacks, typical treatment is high- dose

intravenous corticosteroids. Plasma exchange may be effective in patients who suffer acute severe attacks that do not response to intravenous corticosteroids. For long-term control of the disease a variety of immunosuppressive drugs are utilized by providers as first-line therapy. While all are considered off- label use, corticosteroids, azathioprine, mycophenolate mofetil, and rituximab are treatments prescribed as preventative therapy.

Immunoglobulin G4-related disease (IgG4-RD) is an immune-mediated condition that causes swelling or masses in various organs, along with specific types of tissue inflammation and scarring. Diagnosis is based on a combination of clinical presentation, elevated serum IgG4 levels (present in ~60–70% of patients), and characteristic histopathology, as outlined by the 2019 ACR/EULAR classification criteria. First-line treatment typically involves systemic glucocorticoids daily, tapered gradually over 3–6 months depending on response. Close monitoring for disease relapse and organ dysfunction is essential, as untreated IgG4-RD can lead to irreversible fibrosis and organ failure.

The efficacy of Uplizna for the treatment of IgG4-RD was established in Study 2 (NCT04540497), a randomized, double-blind, multicenter, 52-week placebo-controlled trial that enrolled 135 adult patients who were newly diagnosed or had recurrent IgG4-RD that required glucocorticoid (GC) treatment at screening or had confirmed history of organ involvement at any time in the course of disease. The concomitant use of biologic and non-biologic immunosuppressive agents was prohibited during the blinded phase of the trial. Of the 135 enrolled IgG4-RD patients, 68 patients were randomized to receive Uplizna and 67 were randomized to receive placebo. Patients were at a uniform 20 mg per day dose of glucocorticoids at the time of randomization and then began a prespecified taper of 5 mg dose every two weeks until discontinuation at the end of 8 weeks. The use of glucocorticoids during the trial was permitted for premedication for investigational treatment, treatment for a relapse and in certain situations other than an IgG4-RD flare. Uplizna was administered according to the recommended dosage regimen. Disease flare was defined as new/worsening signs or symptoms that were positively adjudicated and warranted treatment by the investigator. All potential flares were assessed by the investigator and subsequently reviewed by a blinded, independent, adjudication committee, who determined whether the flare met one or more of the protocol-defined, organ-specific flare diagnostic criteria. The primary efficacy endpoint was the time to First Treated and Adjudication Committee (AC)-determined IgG4-RD flare within the 52-week RCP. The time to the First Treated and AC determined IgG4-RD flare was significantly longer in the Uplizna group, compared with the placebo group. Uplizna reduced the risk of treated and AC-determined IgG4-RD flare by 87%, compared with placebo (hazard ratio: 0.13; $p < 0.0001$). For all patients in the trial, the mean (SD) total GC use for IgG4-RD control per patient other than the planned GC taper was lower in the UPLIZNA-treated group compared with the placebo treated group, with a mean (SD) of 118.25 (438.97) mg prednisone equivalent versus 1384.53 (1723.26) mg prednisone equivalent, respectively during the RCP. Forty-two (62.7%) placebo treated patients and 7 (10.3%) Uplizna-treated patients received GC for IgG4-RD control other than the planned GC taper. The mean (SD) total GC use per patient for the 42 placebo treated patients was 2202.76 (1709) mg prednisone equivalent and for the 7 Uplizna-treated patients was 1148.71 (878) mg prednisone equivalent.

Myasthenia gravis (MG) is a rare autoimmune disorder that occurs when a patient's own antibodies block neuromuscular transmission, leading to weakness in skeletal muscles. The condition is characterized by a distinctive pattern of muscle strength reduction with repeated use, which improves after a period of rest. Myasthenia gravis is normally categorized into two clinical types: generalized myasthenia gravis (gMG) and ocular myasthenia gravis. While ocular MG only affects the muscles that are involved with the eyes and eyelids, gMG affects muscles throughout the whole body, and generally gets worse with age. There is currently no cure for gMG, but treatment options are available. To treat MG, cholinesterase inhibitors like pyridostigmine are typically used as a first- line approach. Glucocorticoids may also be administered initially due to their rapid onset, but some patients may not respond well or experience intolerable side effects. In such cases, nonsteroidal immunosuppressive drugs like azathioprine or mycophenolate can be considered to replace or reduce glucocorticoid doses. However, the effects of these drugs may take several months to be seen, and therefore, bridging therapy using IV immune globulin (IVIG) or plasma exchange is often necessary.

The efficacy of Uplizna for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive was established in Study 3 (NCT04524273), a randomized, double-blind, multicenter, placebo-controlled trial. The randomized, controlled treatment period was 52 weeks for the anti-AChR antibody positive population and 26 weeks for the anti-MuSK antibody positive population. The 23 of 27 primary analysis was conducted after week 26 in both populations. Uplizna was administered according to the recommended dosage regimen. Patients met the following eligibility criteria: Presence of autoantibodies against AChR or MuSK, Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, Myasthenia Gravis-Activities of Daily Living (MG-ADL) score between 6 and 10 with > 50% of this score attributed to non-ocular items or an MG-ADL score ≥ 11, Quantitative Myasthenia Gravis (QMG) score of ≥ 11, On a stable dose of a corticosteroid or a specified non-steroidal immunosuppressive therapy, or a combination of both prior to randomization. In Study 3, a total of 238 patients with gMG were randomized in a 1:1 ratio to receive Uplizna or placebo. The majority of patients, 80% (n=190) were anti-AChR antibody positive and 20% (n=48) were anti-MuSK antibody positive. Mean MG-ADL score at baseline was 9.1 and mean QMG score at baseline was 17.0. At baseline, approximately 79% of patients received acetylcholinesterase inhibitors, 64% of patients received corticosteroids only, 7% of patients received non-steroidal immunosuppressive therapy only, and 29% of patients received corticosteroids and 1 nonsteroidal immunosuppressive therapy. The efficacy of Uplizna was measured using MG-ADL scale, which assesses the impact of gMG on daily functions of 8 signs or symptoms that are typically affected in gMG. The total MG-ADL score ranges from 0 to 24, with higher scores indicating more impairment. The primary efficacy endpoint was the change from baseline in the MG-ADL score at week 26, in the overall population. A statistically significant difference favoring Uplizna was observed in the mean change from baseline in MG-ADL total score (−4.2 points in the Uplizna-treated group compared to −2.2 points for placebo, difference of −1.9, 95% CI: −2.9, −1.0; p-value < 0.0001). The secondary endpoint was the change from baseline in the QMG score at week 26 in the overall population. The QMG score is a 13-item categorical grading system that assesses muscle weakness. A total possible score ranges from 0 to 39, where higher scores indicate more severe impairment. A statistically significant difference favoring Uplizna was observed in the mean change from baseline in QMG total score in the overall population (-4.8 points in the Uplizna-treated group compared to -2.3 for placebo, difference -2.5, 95% CI: -3.8, -1.2; p-value = 0.0002).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Uplizna (inebilizumab-cdon) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Uplizna (inebilizumab-cdon) include: previous life-threatening infusion reaction to Uplizna, active hepatitis B infection, active or untreated latent tuberculosis.

OTHER SPECIAL CONSIDERATIONS:

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of Uplizna. The safety of immunization with live or live-attenuated vaccines following Uplizna therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1823	Injection, inebilizumab-cdon, 1 mg

AVAILABLE DOSAGE FORMS:
Uplizna SOLN 100MG/10ML (10 MG/ML) single-dose vial

REFERENCES

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12. Myasthenia Gravis Foundation of America. MGFA Clinical Classification. https://myasthenia.org/Portals/0/MGFA%20Classification.pdf

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Background References	Q1 2026

REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Appendix References	Q3 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Drug Class References	Q3 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Other Special Considerations Available Dosage Forms	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file