UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Uplizna Utilization Management Medical Policy
- Uplizna® (inebilizumab-cdon intravenous infusion – Amgen/Horizon)

REVIEW DATE: 01/21/2026; selected revision 07/08/2026

OVERVIEW

Uplizna, a CD19-directed cytolytic antibody, is indicated for the following uses:[1]

- **Generalized myasthenia gravis** (gMG), in adults who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive.
- **Immunoglobulin G4-related disease** (IgG4-RD) in adults.
- **Neuromyelitis optica spectrum disorder** (NMOSD) in adults who are anti-aquaporin-4 antibody positive.

Dosing

For the approved indications, the recommended dose of Uplizna is an initial dose of 300 mg administered as an intravenous (IV) infusion, followed by a second 300 mg IV infusion 2 weeks after the first dose.[1] Subsequent doses, starting 6 months after the first infusion, are single 300 mg IV infusions every 6 months.

Disease Overview

gMG

Myasthenia gravis is a chronic autoimmune neuromuscular disease that causes weakness in the skeletal muscles, which are responsible for breathing and moving parts of the body, including the arms and legs.[2] Myasthenia gravis is caused by the production of pathogenic immunoglobulin G (IgG) autoantibodies against neuromuscular junction components (AChR, MuSK, and low density lipoprotein receptor-related protein 4).[3] Approximately 85% of patients with myasthenia gravis are anti-AChR antibody positive and approximately 5% to 8% of patients are anti-MuSK antibody positive.[4] The result of the antibodies at the junction is unsuccessful nerve transmission and deficiency or weakness of muscle contractions.[3] The hallmark of myasthenia gravis is muscle weakness that worsens after periods of activity and improves after periods of rest.[2] Certain muscles such as those that control eye and eyelid movement, facial expression, chewing, talking, and swallowing are often involved in the disorder; muscles that control breathing and neck and limb movements may also be affected. MuSK is rare and frequently more severe subtype of myasthenia gravis. Symptomatic treatment with acetylcholinesterase inhibitors (pyridostigmine) is generally unsatisfactory and may be deleterious in MuSK.[16]

IgG4-RD

IgG4-RD (also known as IgG4-related systemic disease, hyper-IgG4 disease, IgG4-related autoimmune disease, IgG4-associated disease, IgG4-related sclerosing disease, and IgG4-syndrome) is a rare, progressive, highly destructive, autoimmune, fibroinflammatory disease.[5,6] The incidence rate was estimated to be 1.39 per 100,000 person-years in 2019 and the point prevalence was 5.3 persons per 100,0000. The disease can affect nearly any organ system and typically, multiple organs are affected simultaneously. Approximately 40% of patients present with clinically evident disease in a single organ and approximately 60% to 90% of patients present with disease in more than one organ. Although any organ can be affected; the most commonly affected organs include the aorta, bile ducts, kidneys, lacrimal glands, orbits, pachymeninges, pancreas, retroperitoneum, major salivary glands (submandibular, parotid, sublingual), and thyroid gland (Riedel's thyroiditis).[7]

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The disease course is unpredictable with recurrent flares that cause functional and structural damage in the affected organs.[5,6] If IgG4-RD is not treated, major organ dysfunction and failure can result. Diagnosis of IgG4-RD is challenging as there is no single definitive diagnostic test. The 2019 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification criteria for IgG4-RD note that although biopsies are useful in diagnosing IgG4-RD, not all patients will have a biopsy.[7] In addition, not all patients with IgG4-RD will have elevated serum immunoglobulin G4 (IgG4) levels. Therefore, diagnosis of IgG4-RD relies on a combination of clinical and serological features as well as radiological and histological findings.[5-7] Since patients may present with a wide range of clinical manifestations and symptoms, a multidisciplinary approach involving different physician specialties may be needed to accurately identify the condition.

NMOSD
NMOSD is a rare, relapsing, autoimmune central nervous system inflammatory disorder that can lead to significant morbidity and mortality.[8,9] The predominant symptoms are inflammation of the optic nerve (optic neuritis) and inflammation of the spinal cord (myelitis). Optic neuritis may lead to pain inside the eye and can progress to blindness. Myelitis tends to affect some, and often all, motor, sensory, and autonomic functions (bladder and bowel). Affected patients may experience pain in the spine or limbs, mild to severe paralysis of the lower limbs, and loss of bowel and bladder control.

Clinical Efficacy - gMG
The efficacy of Uplizna for the treatment of gMG in adults who are anti-AChR or anti-MuSK antibody positive was established in a randomized, double-blind, multicenter, placebo-controlled trial (published) [n = 238].[1,10] Enrolled patients had 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, and quantitative myasthenia gravis score of ≥ 11; and patients had to be on a stable dose of a corticosteroid or a specified non-steroidal immunosuppressive therapy, or a combination of both prior to randomization. The majority of the patients (80%) were anti-AChR antibody positive and 20% were anti-MuSK antibody positive. The primary efficacy endpoint was the change from baseline in the MG-ADL score at Week 26; the change was statistically significantly greater in the Uplizna group vs. placebo: -4.2 points vs. -2.2 points, respectively (difference of -1.9) [$P < 0.0001$].

Recommendations
gMG
An international consensus guidance for the management of myasthenia gravis was published in 2016.[11] The guidelines recommend pyridostigmine for the initial treatment in most patients with myasthenia gravis. The ability to discontinue pyridostigmine can indicate that the patient has met treatment goals and may guide the tapering of other therapies. Corticosteroids or immunosuppressant therapy should be used in all patients with myasthenia gravis who have not met treatment goals after an adequate trial of pyridostigmine. Nonsteroidal immunosuppressant agents include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, and tacrolimus. It is usually necessary to maintain some immunosuppression for many years, sometimes for life. Plasma exchange and intravenous immunoglobulin can be used as short-term treatments in certain patients. A 2020 update to these guidelines provides new recommendations for methotrexate, rituximab, and eculizumab intravenous infusion (Soliris®, biosimilars).[12] All recommendations should be considered extensions or additions to recommendations made in the initial international consensus guidance (2016). Oral methotrexate may be considered as a steroid-sparing agent in patients with generalized myasthenia gravis who have not tolerated or responded to steroid-sparing agents. Rituximab should be considered as an early therapeutic option in patients with anti-MuSK antibody-positive myasthenia gravis who have an unsatisfactory response to initial immunotherapy. Eculizumab should be considered in the treatment of severe, refractory, anti-AChR antibody-positive generalized myasthenia gravis.

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IgG4-RD
There are no formal guidelines for the diagnosis and treatment of IgG4-RD.[13] The 2019 ACR/EULAR classification criteria for IgG4-RD note that all patients with the disease had involvement of one or more organs.[7]Treatment is needed to sustain remission and to prevent further organ damage or failure.[5,6] Systemic corticosteroids (used off-label) are the mainstay of treatment. Objective measures of response include tapering or reduction in the corticosteroid dose, reduction in the number of disease flares, increase in the duration of flare-free period, and absence of disease activity.[13,14] Although most patients respond quickly to systemic corticosteroids, disease control is not maintained following corticosteroid taper or discontinuation.[5,6,13] Other therapies that are used off-label to manage patients with IgG4-RD include conventional, synthetic disease-modifying antirheumatic drugs (DMARDs) [including azathioprine, mycophenolate mofetil, methotrexate, leflunomide, and cyclosporine] and anti-CD20 monoclonal antibodies, such as rituximab. Support for these therapies are mostly from case series, retrospective chart analyses, or single-center trials with an open-label, single-arm design.

NMOSD
The Neuromyelitis Optica Study Group (NEMOS) published revised recommendations for the treatment of NMOSD in 2024.[15] The standard of care for the treatment of NMOSD attacks (for both AQP4-IgG-positive and double-negative cases) are high-dose glucocorticoids and/or apheresis therapy. Long term immunotherapy is recommended for patients with AQP4-IgG-positive NMOSD. NEMOS notes the first-choice therapies for the treatment of AQP4-IgG-positive NMOSD are Uplizna, Enspryng® (satralizumab-mwge subcutaneous injection), eculizumab intravenous infusion (Soliris®, biosimilars), Ultomiris® (ravulizumab-cwvz intravenous infusion), and rituximab. The order of preference for these therapies is unclear and further comparative trials and real-world data are needed. The choice of treatment is dependent on several factors, including disease activity and severity, mode and onset of action, possibility to combine it with immunosuppressive drugs, effect on autoimmune and other comorbidities, gender (family planning issues), frequency and route of administration, side effect profile as well as patient and physician preference. In general, if a patient fails a first-choice treatment, another first-choice treatment should be tried; other options include use of a second-choice treatment (azathioprine, mycophenolate mofetil, low-dose oral glucocorticoids) or the addition of a second-choice treatment to the regimen.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Uplizna. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Uplizna as well as the monitoring required for adverse events and long-term efficacy, approval requires Uplizna to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

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RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Uplizna is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Generalized Myasthenia Gravis.** Approve for duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis; OR
       - **b)** Patient has confirmed anti-muscle-specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis; AND
     - **iii.** Patient meets BOTH of the following (a and b):
       - **a)** Myasthenia Gravis Foundation of America class II to IV; AND
       - **b)** Myasthenia Gravis Activities of Daily Living (MG-ADL) total score ≥ 6; AND
     - **iv.** Patient meets ONE of the following (a or b):
       - **a)** Patient has received or is currently receiving pyridostigmine; OR
       - **b)** Patient has a contraindication to pyridostigmine; OR
       - **c)** Patient has anti-MuSK antibody-positive generalized myasthenia gravis; AND
     - **v.** Patient has evidence of unresolved symptoms of generalized myasthenia gravis; AND
       Note: Examples of unresolved symptoms include difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility).
     - **vi.** The medication is being prescribed by or in consultation with a neurologist; OR
   - **B)** Patient is Currently Receiving Uplizna. Approve for 1 year if the patient meets ALL of the following (i, ii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** According to the prescriber, patient is continuing to derive benefit from Uplizna; AND
       Note: Examples of derived benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function.
     - **iii.** The medication is being prescribed by or in consultation with a neurologist

   Dosing. Approve ONE of the following dosing regimens (A or B):
   - **A)** Initial Therapy. Approve the following dosage regimens (i and ii):
     - **i.** Initial dose: 300 mg administered by intravenous (IV) infusion, followed by a second 300 mg dose administered by IV infusion 2 weeks after the first infusion; AND
     - **ii.** Subsequent doses, starting 6 months after the initial infusion, are single 300 mg doses administered by IV infusion every 6 months; OR
   - **B)** Patient is Currently Receiving Uplizna: Approve a single 300 mg dose administered by intravenous infusion every 6 months.

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2. Immunoglobulin G4-Related Disease. Approve if the patient meets ONE of the following (A or B):
Note: Immunoglobulin G4-related disease (IgG4-RD) can be referred as the following: IgG4-related systemic disease, hyper-IgG4 disease, IgG4-related autoimmune disease, IgG4-associated disease, IgG4-related sclerosing disease, and IgG4-syndrome.

A. Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient is ≥ 18 years of age; AND

ii. Patient has had a history of involvement of at least one organ; AND
Note: Examples of organs that are involved include aorta, bile ducts, kidneys, lacrimal glands, orbits, pachymeninges, pancreas, retroperitoneum, major salivary glands (submandibular, parotid, sublingual), and thyroid gland (Riedel's thyroiditis).

iii. Diagnosis of IgG4-RD is confirmed by at least ONE of the following (a, b, or c):

a) Patient meets BOTH of the following ([1] and [2]):

(1) A biopsy of at least one involved organ; AND

(2) Immunostaining confirms presence of IgG-positive cells; OR

b) Imaging of at least one organ or area of the body; OR
Note: Imaging includes computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET).

c) Patient meets BOTH of the following ([1] and [2]):

(1) Patient has elevated IgG4 levels; AND

(2) Patient has histopathologic features of IgG4-RD; AND
Note: Examples of histopathologic features of IgG4-RD include dense lymphocytic infiltrate, dense lymphocytic infiltrate and obliterative phlebitis, dense lymphocytic infiltrate and storiform fibrosis with or without obliterative phlebitis.

iv. Patient meets ONE of the following (a or b):

a) Patient has received or is currently receiving a systemic corticosteroid; OR

b) Patient has had inadequate efficacy, a contraindication, or significant intolerance to a systemic corticosteroid; AND

v. The medication is being prescribed by or in consultation with an endocrinologist, gastroenterologist, immunologist, nephrologist, neurologist, pulmonologist, rheumatologist, or a physician who specializes in treating immune-mediated disorders; OR

B. Patient is Currently Receiving Uplizna. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. According to the prescriber, patient has had clinical benefit from the use of Uplizna; AND
Note: Examples of clinical benefit include reduction in the corticosteroid dose, reduction in the number of disease flares, increase in the duration of flare-free period, and absence of disease activity.

iii. The medication is being prescribed by or in consultation with an endocrinologist, gastroenterologist, immunologist, nephrologist, neurologist, pulmonologist, rheumatologist, or a physician who specializes in treating immune-mediated disorders.

Dosing. Approve ONE of the following dosing regimens (A or B):

A) Initial Therapy. Approve the following dosage regimens (i and ii):

i. Initial dose: 300 mg administered by intravenous (IV) infusion, followed by a second 300 mg dose administered by IV infusion 2 weeks after the first infusion; AND

ii. Subsequent doses, starting 6 months after the initial infusion, are single 300 mg doses administered by IV infusion every 6 months; OR

B) Patient is Currently Receiving Uplizna: Approve a single 300 mg dose administered by intravenous infusion every 6 months.

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3. **Neuromyelitis Optica Spectrum Disorder**. Approve if the patient meets ONE of the following (A or B):
   - **A.** Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Diagnosis of neuromyelitis optica spectrum disorder was confirmed by blood serum test for anti-aquaporin-4 antibody positive disease; AND
     - **iii.** The medication is being prescribed by or in consultation with a neurologist; OR
   - **B.** Patient is Currently Receiving Uplizna. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Diagnosis of neuromyelitis optica spectrum disorder was confirmed by blood serum test for anti-aquaporin-4 antibody positive disease; AND
     - **iii.** According to the prescriber, patient has had clinical benefit from the use of Uplizna; AND
       Note: Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function), and a slowing progression in symptoms.
     - **iv.** The medication is being prescribed by or in consultation with a neurologist.

   Dosing. Approve ONE of the following dosing regimens (A or B):
   - **A)** Initial Therapy. Approve the following dosage regimens (i and ii):
     - **i.** Initial dose: 300 mg administered by intravenous (IV) infusion, followed by a second 300 mg dose administered by IV infusion 2 weeks after the first infusion; AND
     - **ii.** Subsequent doses, starting 6 months after the initial infusion, are single 300 mg doses administered by intravenous infusion every 6 months; OR
   - **B)** Patient is Currently Receiving Uplizna: Approve a single 300 mg administered by intravenous infusion every 6 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Uplizna is not recommended in the following situations:

1. **Concomitant Use With a Rituximab Product, a Complement Inhibitor, a Neonatal Fc Receptor Blocker, or Enspryng (satralizumab-mwge subcutaneous injection).** There is no evidence to support concomitant use of Uplizna with a rituximab product, a complement inhibitor, a neonatal Fc receptor blocker, or Enspryng.
   Note: Examples of complement inhibitors are eculizumab intravenous infusion (Soliris, biosimilars), Ultomiris (ravulizumab-cwvz intravenous infusion), and Zilbrysq (zilucoplan subcutaneous injection).
   Note: Examples of neonatal Fc receptor blockers are Imaavy (nipocalimab-aahu intravenous infusion), Rystiggo (rozanolixizumab-noli subcutaneous infusion), Vyvgart (efgartigimod alfa-fcab intravenous infusion), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Conditions Not Recommended for Approval:** Ultomiris (ravulizumab-cwvz intravenous infusion) received FDA approval for treatment of NMOSD and was added to the criterion "Concomitant Use with a Rituximab Product, Enspryng (satralizumab-mwge subcutaneous injection), or Soliris (eculizumab intravenous infusion)".	04/10/2024
Annual Revision	**Conditions Not Recommended for Approval:** Soliris (eculizumab intravenous infusion) was changed to add biosimilars; new verbiage reads "eculizumab intravenous infusion (Soliris, biosimilars)".	04/02/2025
Selected Revision	**Immunoglobulin G4-Related Disease:** This condition and criteria for approval were added to the policy. **Neuromyelitis Optica Spectrum Disorder:** The dosing section was revised to clarify dosing recommendations for initial treatment and for patients continuing treatment.	05/21/2025

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HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Immunoglobulin G4-Related Disease:** Initial Therapy: Criterion that required patient to have serum IgG level > 135 mg/dL or two of the following three criteria (dense lymphocyte and plasma cell infiltration with fibrosis, ratio of IgG4-positive plasma cells/ IgG-positive cells > 40% and the number of IgG4-positive plasma cells > 10 per high powered field, and typical tissue fibrosis, particularly storiform fibrosis, or obliterative phlebitis) was removed. Regarding the Note of examples of organs that are involved, "orbital adnexal structures" was removed; the qualifier "major" was added to "salivary glands" along with examples "(submandibular, parotid, sublingual)"; and "bile ducts, orbits, lacrimal glands, aorta, pachymeninges, thyroid gland (Reidel's thyroiditis" were added. Neurologist and pulmonologist were added to the list of specialists. Patient is Currently Receiving Uplizna: Neurologist and pulmonologist were added to the list of specialists.	06/04/2025
Selected Revision	**Immunoglobulin G4-Related Disease:** Initial Therapy: Criterion regarding confirmation of IgG4-RD diagnosis is added. Diagnosis of IgG4-RD is confirmed by at least one of the following: a biopsy of at least one involved organ and immunostaining confirms presence of IgG-positive cells; or imaging; or elevated IgG4 levels and histopathologic features.	07/16/2025
Early Annual Revision	**Generalized Myasthenia Gravis:** This new condition of approval was added to the policy. **Conditions Not Recommended for Approval:** The condition "Concomitant Use with a Rituximab Product, Enspryng (satralizumab-mwge subcutaneous injection), Eculizumab Intravenous Infusion (Soliris, biosimilars), or Ultomiris (ravulizumab-cwvz intravenous infusion" was revised to: "Concomitant Use with a Rituximab Product, a Complement Inhibitor, a Neonatal Fc Receptor Blocker, and Enspryng (satralizumab-mwge subcutaneous injection)". A Note of examples of complement inhibitors and a note of neonatal Fc receptor blockers were added.	01/21/2026
Selected Revision	**Generalized Myasthenia Gravis**. Updated wording from "Patient received or is currently receiving pyridostigmine" to "Patient has received or is currently receiving pyridostigmine." Updated wording from "Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine" to "Patient has a contraindication to pyridostigmine." Added a criterion to bypass the trial of pyridostigmine if the patient has anti-muscle-specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis.	07/08/2026

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