PHARMACY POLICY STATEMENT
TRICARE

DRUG NAME	Uplizna (inebilizumab-cdon)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

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, and generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive.
Neuromyelitis optica spectrum disorder (NMOSD) is a rare, autoimmune disease of the central nervous system that primarily attacks the optic nerves and spinal cord leading to blindness and paralysis.
Immunoglobulin G4-related disease (IgG4-RD) is a multi-organ inflammatory disease characterized by high levels of IgG4 and tumor-like masses. It most commonly affects the pancreas, kidneys, orbital structures, salivary glands, and retroperitoneum.
Myasthenia gravis is an autoimmune disorder affecting the neuromuscular junction, characterized by muscle weakness and fatigue. The cause is an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction, most commonly the acetylcholine receptor.

Uplizna (inebilizumab-cdon) will be considered for coverage when the following criteria are met:

Neuromyelitis Optica Spectrum Disorder (NMOSD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of NMOSD and is seropositive for aquaporin-4 (AQP4) IgG antibodies; AND
4. Member has had 1 or more relapses within the past year; AND
5. Member has tried and failed rituximab for at least 6 months (requires prior auth); AND
6. Member has tested negative for hepatitis B and tuberculosis within the past year or there is attestation they will be tested before starting treatment.
7. **Dosage allowed/Quantity limit:** 300mg IV infusion followed two weeks later by a second 300 mg infusion. Subsequently, (starting 6 months from the first infusion): 300 mg every 6 months.
   QL: 3 vials every 6 months (maintenance)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document disease stabilization, symptom improvement, and/or reduced frequency of relapses compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Immunoglobulin G4-related disease (IgG4-RD)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist, immunologist, endocrinologist, hepatologist or nephrologist; AND
3. Member has a diagnosis of IgG4-RD with involvement of at least **TWO** organ systems; AND
4. Member is experiencing or has recently experienced a flare requiring initiation or continuation of glucocorticoids; AND
5. Member is refractory to glucocorticoids (including glucocorticoid-dependent patients who cannot reduce dose without flare); AND
6. Member has tested negative for hepatitis B and tuberculosis within the past year or there is attestation they will be tested before starting treatment.
7. **Dosage allowed/Quantity limit:** 300 mg IV infusion followed two weeks later by a second 300 mg infusion. Subsequently, (starting 6 months from the first infusion): 300 mg every 6 months.
   QL: 3 vials every 6 months (maintenance)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization:**
1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares and/or decreased steroid use, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Generalized Myasthenia Gravis (gMG)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of MGFA class II-IV myasthenia gravis (see appendix); AND
4. Lab result in chart notes shows the member is seropositive for AChR or MuSK antibodies; AND
5. Member has tried and failed at least 1 conventional therapy:
   a) pyridostigmine
   b) corticosteroid for at least 4 weeks
   c) non-steroid immunosuppressant (e.g., azathioprine) for at least 6 months; AND
6. Member has tested negative for hepatitis B and tuberculosis within the past year or there is attestation they will be tested before starting treatment.

7. **Dosage allowed/Quantity limit:** 300mg IV infusion followed two weeks later by a second 300 mg infusion. Subsequently, (starting 6 months from the first infusion): 300 mg every 6 months. QL: 3 vials every 6 months (maintenance)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document clinically meaningful improvement in symptom severity and daily functioning compared to pre-treatment baseline (e.g., improved MG-ADL or QMG scores).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Scenarios that do not meet the above requirements may be considers Uplizna (inebilizumab-cdon) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/02/2020	New policy for Uplizna created.
07/17/2023	Transferred to new template. Corrected QL.
04/22/2024	Removed azathioprine, mycophenolate trial options (rituximab more effective per guidelines).
05/15/2025	Updated references. Added Immunoglobulin G4-related disease diagnosis.
02/16/2026	Added section for new gMG indication.

Appendix:

MG Foundation of America (MGFA) Clinical Classification	
Class I	any ocular weakness; all other muscle strength is normal
Class II	mild weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class III	moderate weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class IV	severe weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class V	defined by intubation, with or without mechanical ventilation

References:

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11. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124
12. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. *J Clin Med*. 2022;11(6):1597. Published 2022 Mar 14. doi:10.3390/jcm11061597

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