Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Uplizna® (inebilizumab-cdon)

Effective: April 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Uplizna for NMOSD was based on the N-MOmentum trial which was stopped before complete enrollment, as recommended by the independent data-monitoring committee, because to a clear demonstration of efficacy. Results showed that treatment with Uplizna in anti-AQP4 antibody positive patients reduced the risk of an NMOSD relapse by 77% when compared to the placebo treatment group. A smaller proportion of patients had an attack when treated with Uplizna compared to placebo (11.2 vs 42.3%). There was no evidence of a benefit in patients who were anti-AQP4 antibody negative.

The approval of Uplizna for IgG4-RD was supported by results from the Phase 3 multicenter, double-blind, randomized, placebo-controlled MITIGATE trial, which evaluated the safety and efficacy of Uplizna compared with placebo in adults with active IgG4-RD. Uplizna significantly reduced the risk of disease flares and increased the likelihood of flare-free complete remission at 1 year compared with placebo.

Uplizna was approved for generalized myasthenia gravis (gMG) based on the Phase 3 MINT trial, which included adult patients with gMG who were anti–AChR Ab+ or anti–MuSK Ab+. Eligibility criteria at screening and randomization included an MGFA classification of class II, III or IV disease; Myasthenia Gravis-Activities of Daily Living (MG-ADL) score between 6 and 10 with greater than 50% of this score attributed to non-ocular items, or an MG-ADL score of at least 11; and a Quantitative Myasthenia Gravis (QMG) score of at least 11. Participants who received Uplizna had a greater reduction in their MG-ADL scores than those who received placebo.

Food and Drug Administration - Approved Indications

Uplizna (inebilizumab-cdon) is a CD19-directed cytolytic antibody indicated for 1) the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive and 2) The treatment of immunoglobulin G4-related disease (IgG4-RD) and 3) anti-acteylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive generalized myasthenia gravis (gMG)

Clinical Guideline Coverage Criteria

The plan may authorize coverage of **Uplizna** for Members when **ALL** of the following criteria are met:

Neuromyelitis Optica Spectrum Disorder (NMOSD)

1. Documented diagnosis of neuromyelitis optica spectrum disorder

AND

2. Documentation of a positive serologic test for anti-aquaporin-4 antibodies

AND

3. The prescribing physician is a neurologist or an ophthalmologist

Immunoglobulin G4-related Disease (igG4-RD)

1. Documented diagnosis of immunoglobulin G4-related disease (IgG4-RD)

AND

2. Member meets the 2019 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR)

classification criteria for IgG4-RD, as evidenced by all of the following:

a. Involvement of at least one (1) of eleven (11) possible organs in a manner consistent with IgG4-RD
b. No exclusion criteria are present
c. Total inclusion criteria points is at ≥ 20

AND

3. Member is experiencing or recently experienced IgG4-RD flare that requires initiation or continuation of glucocorticoid treatment

AND

4. IgG4-RD affecting at least 2 organs/sites at any time

AND

5. Member is refractory to or is unable to use glucocorticoid

AND

6. Member will not be used in combination with rituximab

AND

7. Member is at least 18 years of age or older

AND

8. The prescribing physician is a rheumatologist, immunologist, endocrinologist, nephrologist, hepatologist, or provider with experience in treating Immunoglobulin G4-related disease (IgG4-RD)

Generalized Myasthenia Gravis (gMG)

Initial:

1. Documented diagnosis of gMG

AND

2. The prescribing physician is a neurologist

AND

3. Documentation of a positive serologic test for one (1) of the following:
   a. Anti-acetylcholine antibodies
   b. Anti-muscle-specific tyrosine kinase antibodies

Reauthorization:

1. Documented diagnosis of gMG

AND

2. The prescribing physician is a neurologist

AND

3. Documentation of a positive serologic test for one (1) of the following:
   a. Anti-acetylcholine antibodies
   b. Anti-muscle-specific tyrosine kinase antibodies

AND

4. Documentation the Member has experienced a therapeutic response as defined by an improvement of Myasthenia Gravis Activities of Daily Living (MG-ADL) total score from baseline

Limitations

- Initial coverage of Uplizna for generalized myasthenia gravis will be authorized for 12 months. Reauthorization will be provided in 12-month intervals.
- Members new to the plan and stable on Uplizna for generalized myasthenia gravis should be reviewed against the reauthorization criteria

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1823	Injection, inebilizumab-cdon, 1 mg

References

1. Kessler RA, et al. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. Curr Treat Options Neurol. 2016;18(1):2
2. Cree BAC, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): a double-blind, randomized placebo-controlled phase 2/3 trial. The Lancet. 2019;394(10206):1352-1363.
3. Flanagan EP, et al. Epidemiology of aquaporin-4 Autoimmunity and Neuromyelitis Optica Spectrum. Ann Neurol. 2016;79(5):775-783.
4. Uplizna (inebilizumab-cdon) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc..; April 2025.
5. Wallace, Zachary S., et al. "The 2019 American College of Rheumatology/European League against rheumatism classification criteria for lgG4-related disease." Annals of the rheumatic diseases 79.1 (2020): 77-87.
6. Narayanaswami P, et al. International Consensus Guidance for Management of Myasthenia Gravis. 2020 Update. Neurology. 2021;96:114-122

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed the Limitations The health plan may authorize Uplizna (inebilizumab-cdon) for up to 12 months when coverage criteria are met and Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan. Added provider specialty requirements. Minor wording updates (eff 2/1/2024).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- September 10, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- December 8, 2025: Added coverage criteria for Uplizna expanded indication of Immunoglobulin G4-related disease. (effective 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)
- March 10, 2026: Added coverage criteria for generalized myasthenia gravis (effective 4/1/26)
- March 2026: Joint Medical Policy and Health Care Services UM Committee review

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.