Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: August 1, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ 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

Food and Drug Administration - Approved Indications

Uplizna (enebilizumab-cdon) 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
- Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive

Clinical Guideline Coverage Criteria

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

Neuromyelitis optica spectrum disorder

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

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

Initial Authorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

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

AND

3. Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV generalized myasthenia gravis

AND

4. Documentation of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 6

AND

5. The prescribing physician is a neurologist

AND

6. Documentation of **one (1)** of the following:
    a. Persistent symptoms that limit function following a previous trial of immunosuppressive therapy consisting of a glucocorticoid in combination with at least one other immunotherapeutic agent (e.g., azathioprine, mycophenolate, cyclosporine, tacrolimus)
    b. Ongoing rescue therapy with intravenous immunoglobulin or plasma exchange while receiving immunosuppressive therapy
    c. Clinical rationale to avoid immunosuppressive therapy with glucocorticoids and other immunotherapeutic agents (e.g., azathioprine, mycophenolate, cyclosporine, tacrolimus)

Reauthorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

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

AND

3. The prescribing physician is a neurologist

AND

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

Limitations

- Combination therapy with other neuromyelitis optica spectrum disorder disease-modifying treatments such as Soliris or Enspryng will not be authorized.
- For generalized myasthenia gravis, initial coverage of Uplzina will be authorized for 6 months. Reauthorization of Uplizna will be provided in 12-month intervals. Members new to the plan stable on Uplizna should be reviewed against 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. Cree BA, Bennett JL, Kim HJ, 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):1352-63.
2. Glisson CC. Neuromyelitis optica spectrum disorders (NMOSD): Treatment and prognosis. UpToDate. Wolters Kluwer Health. January 2022.
3. Uplizna (inebilizumab-cdon) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc..; December 2025.
4. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015; 85:177-189.
5. Wallace, Zachary S., et al. "The 2019 American College of Rheumatology/European League against rheumatism classification criteria for IgG4-related disease." Annals of the rheumatic diseases 79.1 (2020): 77-87.

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: No changes
- September 10, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: Added coverage criteria for Uplizna's expanded indication of Immunoglobulin G4-related disease. (eff 10/1/25)
- July 14, 2026: Added coverage criteria for Uplizna's expanded indication of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive. Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from "Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans" to "Tufts Health Together- MassHealth Accountable Care Partnership Plans." (eff 8/1/26).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.