Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Imaavy (nipocalimab)

Effective: October 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

Myasthenia gravis (MG) is an autoimmune disorder characterized by muscle weakness and fatigue. There are two classifications of MG: ocular and general. The degree of muscle weakness can fluctuate and vary in severity from person to person; however, it will generally improve with rest and worsen with physical activity. Mostly patients with MG develop autoantibodies that attack the acetylcholine receptor (AChR), blocking or destroying the receptors, which prevents muscles from contracting. Treatment decisions for generalized myasthenia gravis (gMG) are based on knowledge of the natural history of disease in each patient and the predicted response to a specific form of therapy. Goals are individualized based on disease severity, patient age and sex, and the degree of functional impairment.

Food and Drug Administration - Approved Indications

Imaavy (nipocalimab) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients ≥12 years of age who are anti–acetylcholine receptor (AChR) or anti–muscle-specific tyrosine kinase (MuSK) antibody-positive (Ab+).

Clinical Guideline Coverage Criteria

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

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 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 Imaavy for generalized myasthenia gravis will be authorized for 6 months. Reauthorization of Imaavy will be provided for 12-month intervals.
- Members new to the plan stable on Imaavy should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9256	Injection, nipocalimab-aahu, 3 mg

References

1. Imaavy [package insert]. Horsham, PA: Janssen Biotech, Inc; 2025 Apr.
2. Narayanaswami P, et al. International Consensus Guidance for Management of Myasthenia Gravis. 2020 Update. Neurology. 2021;96:114-122

Approval And Revision History

February 10, 2026: Reviewed by Pharmacy and Therapeutics Committee (P&T) (Effective retro 1/1/26)

Subsequent endorsement date(s) and changes made:

- February 2026: Administrative update: removed Carelink from template.
- July 14, 2026: Added documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV generalized myasthenia gravis, Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 6, and updated requirements to establish refractory disease of generalized myasthenia gravis. Administrative updates: Minor formatting updates. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.” (eff 10/1/26). Updated One Care Unify to Tufts Health One Care on template to reflect change.

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.