Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Imaavy™ (nipocalimab)

Effective: January 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

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

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

☐ Tufts Health Together – MassHealth MCO Plan and 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. Most 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

Approval of Immavy was supported by the ongoing Phase 3 Vivacity-MG3 study (NCT04951622), which enrolled 199 adults with gMG, 153 of whom were Ab+. Efficacy of Imaavy was measured using the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale. Patients who received Imaavy plus standard-of-care (SOC) therapy had a statistically significant improvement in MG-ADL scores versus patients who received SOC plus placebo at 24 weeks. Patients who received Imaavy also had a reduction in autoantibody levels of ≥75% from the first dose through 24 weeks.

Food and Drug Administration - Approved Indications

Imaavy 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

Initial Authorization Criteria

1. Documented diagnosis of generalized myasthenia gravis 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 Criteria

1. Documented diagnosis of generalized myasthenia gravis 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 Imaavy for generalized myasthenia gravis will be authorized for 6 months. Reauthorization of Immavy will be provided for 12-month intervals,
- Members new to the plan stable on Immavy 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

December 8, 2025: Reviewed by the Medical Policy Approval Committee (MPAC).

December 9, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T).

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: Dr ug 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.