Imaavy™ (nipocalimab-aahu)
(Intravenous)

Effective date: 11/01/2025
Dates Reviewed: 10/2025, 04/07/2026
Medical Scope: Medicaid, Commercial, Medicare

I. Length of Authorization [1]

Initial coverage will be provided for 6 months. Coverage may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1,200 billable units (3,600 mg) initially then 600 billable units (1,800 mg) every two weeks thereafter

III. Summary of Evidence

Imaavy (nipocalimab) is a neonatal fragment crystallizable receptor (FcRn) blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti–acetylcholine receptor (AChR) or anti–muscle-specific tyrosine kinase (MuSK) antibody-positive (Ab+). Imaavy's approval was based on the Vivacity-MG3 trial, a phase 3 randomized, double-blind, placebo-controlled 24-week trial. The trial enrolled 196 adults with Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV, MG activities of daily living (MG-ADL) score of ≥6, and on stable dose of standard of care MG therapy (e.g., acetylcholinesterase (AChE) inhibitors, steroids or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone). The patients had a median MG-ADL score of 9, with a possible score range from 0 to 24, with higher scores indicating greater impairment/loss of daily function. Imaavy treatment significantly reduced the MG-ADL score by a mean of -4.7, compared with placebo -3.3 (treatment difference -1.5, p = 0.002) at Weeks 22-24. The most common adverse reactions (≥10%) were respiratory tract infections, peripheral edema, and muscle spasms.

IV. Initial Approval Criteria [1]

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Coverage is provided in the following conditions:

Universal Criteria [1,3]

- Member is at least 12 years of age; **AND**

- Prescribed by, or in consultation with, a neurologist; AND
- The member will NOT be using the requested agent in combination with other immunomodulatory biologic therapies (e.g., Rystiggo (rozanolixizumab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), Uplizna (inebilizumab), Zilbrysq (zilucoplan), etc.); **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent

Generalized Myasthenia Gravis (gMG) † Φ [1,3-6,8]

- Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG); **AND**
- Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IVb disease; **AND**
- Member has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies; **AND**
- Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); **AND**
- Member has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 6; **AND**
- The member meets one of the following:
    - The member has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member required chronic intravenous immunoglobulin (IVIG); **OR**
    - The member required chronic plasmapheresis/plasma exchange; **AND**
- The member's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued **OR** discontinuation of the offending agent is NOT clinically appropriate; **AND**
- For adult members with anti-AChR Ab+ gMGthe member had an inadequate response or contraindication to Uplizna (inebilizumab) and Vyvgart (efgartigimod) or Vyvgart Hytrulo (efgartigimod and hyaluronidase); **OR**
- For adult members with anti-MUSK Ab+ gMG, the member had an inadequate response or contraindication to Uplizna (inebilizumab) and Rystiggo (rozanolixizumab); AND
- For adult members anti-AChR Ab+ gMG who require a maintenance dose every 2 weeks requiring 2 vials (>1200mg), the member had an inadequate response or contraindication to Rystiggo (rozanolixizumab) or eculizumab; **AND**
- Prescribed dose provided, and in accordance with FDA-approved labeling based on current documented weight.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

V. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- The member has been previously approved for the requested agent through the plan's Medical Drug Review process (Note: members not previously approved for the requested agent will require initial evaluation review); **AND**
- Prescribed by, or in consultation with, a neurologist; **AND**
- The member will NOT be using the requested agent in combination with other immunomodulatory biologic therapies (e.g., Rystiggo (rozanolixizumab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), Uplizna (inebilizumab), Zilbrysq (zilucoplan), etc.); **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- Prescribed dose provided, and in accordance with FDA-approved labeling based on current documented weight.
- Member has had an improvement (i.e., reduction) of at least 2-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score sustained for at least 4 weeks **Δ**; **AND**
- Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline

  *(**Δ** May substitute an improvement of at least 3-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4 weeks, if available)*

VI. Dosage/Administration [1]

Indication	Dose
Generalized Myasthenia Gravis (gMG)	The recommended initial dosage of Imaavy is 30 mg/kg administered once via intravenous infusion over at least 30 minutes. Two weeks after the initial dosage administer a maintenance dosage of 15 mg/kg via intravenous infusion over at least 15 minutes. Continue the maintenance dosage every two weeks thereafter.

VII. Billing Code/Availability Information

HCPCS Code:

- J9256 – Injection, nipocalimab-aahu, 3 mg; 1 billable unit = 3 mg

NDC(s):

- Imaavy 300 mg/1.62 mL solution in a single-dose vial: 57894-0800-xx
- Imaavy 1,200 mg/6.5 mL solution in a single-dose vial: 57894-0801-xx

VIII. References

1. Imaavy [package insert]. Horsham, PA; Janssen Biotech, Inc., April 2025. Accessed March 2026.
2. Sussman J, Farrugia ME, Maddison P, et al. Myasthenia gravis: Association of British Neurologists' management guidelines. Pract Neurol 2015; 15: 199-206.
3. Narayanaswami P, Sanders D, Wolfe G, Benatar M, et al. International consensus guidance for management of myasthenia gravis, 2020 update. Neurology® 2021;96:114-122. doi:10.1212/WNL.0000000000011124.
4. Antozzi C, Vu PT, Ramchandren S, et al. Safety and efficacy of nipocalimab in adults with generalised myasthenia gravis (Vivacity-MG3): a phase 3, randomised, double-blind, placebo-controlled study. The Lancet Neurology, Volume 24, Issue 2, 105 - 116
5. Jayam-Trouth A, Dabi A, Solieman N, Kurukumbi M, Kalyanam J. Myasthenia gravis: a review. *Autoimmune Dis*. 2012;2012:874680. doi:10.1155/2012/874680
6. Bril V, Druzdz A, Grosskreutz J, et al. Long-term Efficacy and Safety of Symptom-driven Cyclic Rozanolixizumab Treatment in Patients with Generalized Myasthenia Gravis: A Pooled Analysis of a Phase 3 Study and Two Open-label Extension Studies (P1-5.012). Neurology Apr 2023, 100 (17 Supplement 2) 3747; DOI: 10.1212/WNL.0000000000203497
7. Guidon AC, Muppidi S, Nowak RJ, et al. Telemedicine visits in myasthenia gravis: expert guidance and the Myasthenia Gravis Core Exam (MG-CE). Muscle Nerve 2021; 64:270-276
8. Gronseth GS, Barohn R, Narayanaswami P. Practice advisory: Thymectomy for myasthenia gravis (practice parameter update): Report of the Guideline Development, Dissemination, and

Implementation Subcommittee of the American Academy of Neurology. Neurology. 2020;94(16):705. Epub 2020 Mar 25.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington	Novitas Solutions, Inc.

	& Fairfax counties and the city of Alexandria in VA)	
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:
Imaavy was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Imaavy according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.