Medical Policy:

Imaavy (nipocalimab-aahu) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.440	August 7, 2025	August 7, 2025

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Imaavy, a neonatal Fc receptor blocker, is indicated for the treatment of generalized myasthenia gravis in adults and pediatric patients ≥ 12 years of age who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.1

Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

Dosing Limits [Medical Benefit]

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

- 3,600 mg initially then 1,800 mg every two weeks thereafter

Guideline

I. Initial Criteria

Coverage is provided in the following conditions:

1. Patient is at least 12 years of age; **AND**
2. Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Generalized Myasthenia Gravis (gMG)

1. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease §; **AND**
2. Patient has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies; **AND**
3. Patient has had a thymectomy (*Note: Applicable only to patients with AChR positive disease and with thymomas OR non-thymomatous patients who are 50 years of age or younger)*; AND
4. 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
5. Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 3; AND
    - **a.** Patient had an inadequate response to initial therapy based on their antibodies:
        - **i.** AChR+ disease: a minimum one-year trial of concurrent use with an oral corticosteroid plus another immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate, etc.); OR
        - **ii.** MuSK+ disease: a minimum one-year trial with immunosuppressive therapy (e.g., corticosteroids, azathioprine, or mycophenolate) and rituximab; OR
6. Patient required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy

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

§ Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification: [5,6]

− Class I: Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
− Class II: Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

− Class III: Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IIIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IIIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

− Class IV: Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IVa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IVb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

− Class V: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

II. Renewal Criteria

Coverage can be renewed based upon the following criteria:

1. Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: infection, severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, etc.), etc.; **AND**
3. Patient has had an improvement (i.e., reduction) of at least 1-point from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score **Δ**; **AND**
4. 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 1-point from baseline in the Quantitative Myasthenia Gravis (QMG) total score, if available)*

Applicable Procedure Codes

Code	Description
J3590	Unclassified biologics

Applicable NDCs

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

ICD-10 Diagnoses

Code	Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	08/07/2025	New Policy

References

1. Imaavy [package insert]. Horsham, PA; Janssen Biotech, Inc., April 2025. Accessed May 2025.
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.