Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Nipocalimab-aahu (Imaavy™)	**MP-RX-FP-179-25**	☒ **MMM MA** ☒ **MMM MultiHealth**	**10/10/2025** **Last Review Date:** **10/21/2026**	**10/21/2026** **Frequently Revision:** **Annual**

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of Nipocalimab-aahu (Imaavy), a neonatal Fc receptor (FcRn) blocker approved by the Food and Drug Administration (FDA) 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.

Background Information:

Imaavy (nipocalimab-aahu) is a human IgG1 monoclonal antibody that binds to FcRn, resulting in the reduction of circulating IgG levels. Imaavy is intravenously administered through an infusion pump by a healthcare professional once every 2 weeks.

Generalized myasthenia gravis (gMG) is an autoimmune neuromuscular disorder characterized by fluctuating motor weakness causing dyspnea, dysphagia, diplopia, dysarthria, and ptosis. Generalized myasthenia gravis is commonly mediated by IgG autoantibodies directed against the neuromuscular junction. Approximately 95% of patients with generalized myasthenia gravis test positive for antibodies (about 85% antiacetylcholine receptor [AChR]-positive, about 8% anti-muscle-specific tyrosine kinase [MuSK]-positive, and about 1–2% anti-low-density lipoprotein receptor-related protein 4 [LRP4]-positive). Treatment strategies include symptomatic therapy (with anticholinesterase agents such as pyridostigmine), chronic immunotherapy with steroids or other immunosuppressive drugs (such as azathioprine, cyclosporine, or methotrexate), rapid immunotherapy (with plasmapheresis or IV immune globulin), and/or surgical treatment. Imaavy is the first FcRn inhibitor approved for gMG in the pediatric population; and the first FcRn inhibitor administered continuously every 2 weeks. Myasthenia Gravis Foundation of America (MGFA) international consensus guidelines, published prior to the approval of FcRn inhibitors, recommend immunosuppressive drugs and/or corticosteroids for individuals who have not met treatment goals after an adequate trial of pyridostigmine.

Current published evidence for Imaavy includes a phase 3, multicenter, randomized, placebo-controlled trial that enrolled individuals with antibody-positive gMG who had an inadequate response (defined as a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class IIa/b to Iva/b disease and a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥6) to their current, stable standard-of-care therapy for gMG (cholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressants) prior to screening and throughout the study. Nipocalimab or placebo was administered as an add-on treatment to background standard-of-care therapies, with no changes permitted during the double-blind phase. The primary efficacy endpoint was the difference in the least-squares mean change from baseline in the MG-ADL total score between the nipocalimab and placebo groups, averaged over weeks 22, 23, and 24. A clinically meaningful improvement in the MG-ADL response was defined as a reduction of 2 or more points. The trial showed statistically significant improvements in the MG-ADL total score for the nipocalimab group compared to placebo over weeks 22, 23, and 24, meeting the primary efficacy endpoint.

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Approved Indications

A. 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.

Other Uses

A. None.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Nipocalimab-aahu (Imaavy®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Initial requests for Imaavy (nipocalimab-aahu) may be approved if the following criteria are met:

i. Individual is 12 years of age or older; **AND**
ii. Individual has a diagnosis of generalized myasthenia gravis (gMG); **AND**
iii. Documentation is provided that individual has one of the following:
   A. A positive serologic test for the presence of anti-acetylcholine receptor antibodies (AchR); **OR**
   B. A positive serologic test for the presence of anti-muscle-specific tyrosine kinase (MuSK) antibodies; **AND**
iv. Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV disease (Antozzi 2025); **AND**
v. Documentation is provided that individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 6 or higher (Antozzi 2025); **AND**
vi. Individual meets both of the following (A and B):
   A. Individual has had a trial and inadequate response or intolerance to an acetylcholinesterase inhibitor; **OR**
      1. Individual is on a stable dose of an acetylcholinesterase inhibitor; **OR**
      2. Individual has a contraindication to acetylcholinesterase inhibitors; **AND**
   B. Individual has had a trial and inadequate response or intolerance to one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**
      1. Individual is on a stable dose of one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**
      2. Individual has a contraindication to systemic corticosteroids and non-steroidal immunosuppressants

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B. Criteria For Continuation of Therapy

Continuation requests for Imaavy (nipocalimab-aahu) may be approved if the following criteria are met:

i. Individual has experienced a prior clinical response to Imaavy (nipocalimab-aahu) treatment as defined by the following:
   A. Reduction in signs or symptoms that impact daily function; **AND**
   B. Documentation is provided that there is at least a 2-point reduction in MG-ADL total score from pretreatment baseline.

C. Authorization Duration

i. Initial Approval Duration: 26 weeks
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Imaavy (nipocalimab-aahu) may not be approved for the following:

i. Individual is using in combination with maintenance immunoglobulin treatment, eculizumab, ravulizumab, efgartigimod-alfa, rozanolixizumab, zilucoplan, or rituximab; **OR**
ii. If the above criteria are not met and for all other indications (Section A).

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Imaavy (nipocalimab-aahu) 300 mg/1.62 mL (185 mg/mL) single dose vial; 1200 mg/6.5 mL (185 mg/mL) single dose vial	**Initial dose**: One 30 mg/kg IV **Maintenance dosage** (two weeks after the initial dosage): 15 mg/kg IV every 2 weeks

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

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

HCPCS Codes:

Codes	Description
J9256	Injection Nipocalimab-aahu 3 Mg

Reference Information:

1. Antozzi C, Vu T, 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. Lancet Neurol. 2025;24(2):105-116. doi:10.1016/S1474-4422(24)00498-8
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Janssen Biotech, Inc. Imaavy™ (nipocalimab-aahu) injection, for intravenous use: Prescribing Information. Revised April 2025. Accessed July 9, 2026. https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/IMAAVY-pi.pdf
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
6. Narayanaswami P, Sanders DB, Wolfe G, et al for the Task Force of the Myasthenia Gravis Foundation of America (MGFA). International consensus guidance for management of myasthenia gravis 2020 update. Neurology 2021; 96:114-122

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Background Information to add MOA, FDA approved indication and infusion administration information. Updated initial approval duration to 26 weeks. Clarified that Imaavy is administered through an IV infusion in the quantity limits table. Coding Reviewed: no changes. Updated reference information and incorporated new policy template.	10/15/2026	10/21/2026
Select Review	Coding reviewed: J9256 added.	N/A	N/A
Policy Inception	Elevance Health's Medical Policy adoption.	9/22/2025	10/10/2025