Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Nipocalimab-aahu (**Imaavy**)	MP-RX-FP-179-25	☒ MMM MA ☒ MMM Multihealth

Service Category

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

Service Description

This document addresses the use of Nipocalimab-aahu (Imaavy) , a drug approved by the Food and Drug Administration (FDA) for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric members 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Background Information

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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Applicable Codes

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.

HCPCS	Description
J9256	Injection Nipocalimab-aahu 3 Mg

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

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Nipocalimab-aahu (**Imaavy)**

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

A. Criteria For Initial Approval

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

B. Criteria For Continuation of Therapy

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.

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C. Authorization Duration

a. Initial Approval Duration: 6 months
b. 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):

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. 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 infusion **Subsequent doses:** 15 mg/kg every 2 weeks

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. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. 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

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Select Review 1/7/2026	Coding reviewed: J9256 added.	N/A	N/A
Policy Inception 8/18/2025	Elevance Health's Medical Policy adoption.	9/22/2025	10/10/2025