Original Effective Date: 09/10/2025
Current Effective Date: 09/10/2025
Last P&T Approval/Version: 07/30/2025
Next Review Due By: 10/2025
Policy Number: C29627-A

Imaavy (nipocalimab-aahu)

PRODUCTS AFFECTED

Imaavy (nipocalimab-aahu)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Generalized myasthenia gravis (gMG)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. GENERALIZED MYASTHENIA GRAVIS:
   1. Documented diagnosis of generalized myasthenia gravis
      AND
   2. Documentation member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV confirmed by positive serologic test for binding anti-

acetylcholine receptor antibodies (AChR-ab) OR anti-muscle-specific tyrosine kinase (MuSK) antibodies [DOCUMENTATION REQUIRED]
AND

3. Documentation of member's Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score (or other means for treatment plan efficacy monitoring)
AND
4. Documentation of an inadequate treatment response (2 weeks trial period), serious side effects, or contraindication to pyridostigmine AND formulary glucocorticoids
AND
5. Imaavy (nipocalimab-aahu) will not be used concurrently with Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab), Vyvgart/Vyvgart Hytrulo (efgartigimod), or Zilbrysq (zilucoplan)

CONTINUATION OF THERAPY:

A. GENERALIZED MYASTHENIA GRAVIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms as evidenced by ONE of the following:
(a) Improvement (reduction in score) from pre-treatment baseline on the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) assessment OR
(b) Reduction in signs and symptoms of myasthenia gravis OR
(c) Stabilization, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting therapy

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see appendix

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified immunologist, neurologist, or rheumatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

12 years of age and older

QUANTITY:

30 mg/kg administered intravenously once initially, followed by 15 mg/kg administered intravenously every 2 weeks.

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Neonatal Fc Receptor (FcRn) Antagonist

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
State Specific Information
State Marketplace
Texas *(Source: Texas Statutes, Insurance Code)*
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits may not require an enrollee to receive more than one prior authorization annually of the prescription drug benefit for a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that: (A) have a boxed warning assigned by the United States Food and Drug Administration for use; and (B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Myasthenia gravis (MG) is a rare autoimmune disorder that occurs when a patient's own antibodies block neuromuscular transmission, leading to weakness in skeletal muscles. The condition is characterized by a distinctive pattern of muscle strength reduction with repeated use, which improves after a period of rest. Myasthenia gravis is normally categorized into two clinical types: generalized myasthenia gravis (gMG) and ocular myasthenia gravis. While ocular MG only affects the muscles that are involved with the eyes and eyelids, gMG affects muscles throughout the whole body, and generally gets worse with age. There is currently no cure for gMG, but treatment options are available. To treat MG, cholinesterase inhibitors like pyridostigmine are typically used as a first- line approach. Glucocorticoids may also be administered initially due to their rapid onset, but some patients may not respond well or experience intolerable side effects. In such cases, nonsteroidal immunosuppressive drugs like azathioprine or mycophenolate can be considered to replace or reduce glucocorticoid doses. However, the effects of these drugs may take several months to be seen, and therefore, bridging therapy using IV immune globulin (IVIG) or plasma exchange is often necessary. Imaavy (nipocalimab-aahu) is a new, recently FDA-approved medication that is indicated for the treatment of generalized myasthenia gravis. Nipocalimab-aahu is a humanized IgG4 monoclonal antibody that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG, the main antibody responsible for blocking neuromuscular transmission.

The efficacy of Imaavy was established in a 24-week, multicenter, randomized, double-blind, placebo-controlled trial (Study 1; NCT04951622). Eligible participants had MGFA Clinical Classification Class II to IV and a Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of at least 6. All patients were on a stable dose of standard-of-care MG therapies, including acetylcholinesterase inhibitors, steroids, or non-steroidal immunosuppressive therapies.

A total of 196 patients were randomized 1:1 to receive either Imaavy (n=98) or placebo (n=98). Baseline median MG-ADL and Quantitative Myasthenia Gravis (QMG) scores were 9 and 15, respectively. The primary goal of the study was to measure improvement in MG-ADL scores by Week 24. Patients treated with Imaavy showed improvement than those on placebo, with a difference of –1.5 points.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Imaavy (nipocalimab-aahu) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Imaavy (nipocalimab-aahu) include: patients with a history of serious hypersensitivity reaction to nipocalimab or to any of the excipients in Imaavy. However, patients should be delayed administration of Imaavy if they have signs or symptoms consistent with an active infection.

Exclusions/Discontinuation:
During treatment with Imaavy, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding Imaavy until the infection has resolved.

OTHER SPECIAL CONSIDERATIONS:
If a scheduled infusion appointment is missed, the maintenance dosage of Imaavy should be administered as soon as possible. Resume dosing every two weeks thereafter.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Imaavy SOLN 1200MG/6.5ML single-dose vial

REFERENCES

1. Imaavy (nipocalimab-aahu) injection, for intravenous use [prescribing information]. Horsham, PA:

Janssen Biotech, Inc.; April 2025.
2. Antozzi C, Vu T, Ramchandren S, Nowak RJ, Farmakidis C, Bril V, 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.
3. Jaretzki A 3rd, et al. Myasthenia gravis: recommendations for clinical research standards. Task Force of the Medical Scientific Advisory Board of the Myasthenia Gravis Foundation of America. Neurology. 2000;55(1):16–23. doi:10.1212/wnl.55.1.16
4. Myasthenia Gravis Foundation of America. MGFA Clinical Classification. https://myasthenia.org/Portals/0/MGFA%20Classification.pdf

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q3 2025