Clinical Policy: Nipocalimab-aahu (Imaavy)

Reference Number: CP.PHAR.720
Effective Date: 04.30.25
Last Review Date: 05.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Nipocalimab-aahu (Imaavy™) is a neonatal Fc receptor blocker.

FDA Approved Indication(s)

Imaavy is 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.

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that Imaavy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Generalized Myasthenia Gravis (must meet all)**:**

1. Diagnosis of gMG;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 12 years;
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) score ≥ 6 at baseline;
5. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV;
6. Member has positive serologic test for one of the following (a or b):
   a. Anti-AChR antibodies;
   b. Anti-MuSK antibodies;
7. If member has positive serologic test for anti-AChR antibodies: Failure of a cholinesterase inhibitor (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
8. Failure of a corticosteroid (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
9. Failure of at least one immunosuppressive therapy (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;*

**For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*

10. Imaavy is not prescribed concurrently with Bkemv™/Epysqli®/Soliris®, Rystiggo®, Ultomiris®, Vyvgart®, Vyvgart® Hytrulo, or Zilbrysq®;
11. Documentation of member's current weight (in kg);
12. Dose does not exceed both of the following (a and b):
    a. Loading dose: 30 mg/kg once;
    b. Maintenance dose: 15 mg/kg 2 weeks after the loading dose and every 2 weeks thereafter.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
    b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Generalized Myasthenia Gravis (must meet all)**:**

1. Member meets one of the following (a or b):
    a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
    b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidenced by a 2-point reduction in MG-ADL total score from baseline;
3. Imaavy is not prescribed concurrently with Bkemv/Epysqli/Soliris, Rystiggo, Ultomiris, Vyvgart, Vyvgart Hytrulo, or Zilbrysq;
4. Documentation of member's current weight (in kg);
5. If request is for a dose increase, new dose does not exceed 15 mg/kg every 2 weeks.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AChR: acetylcholine receptor
FDA: Food and Drug Administration
gMG: generalized myasthenia gravis
MG-ADL: Myasthenia Gravis-Activities of Daily Living
MGFA: Myasthenia Gravis Foundation of America
MuSK: muscle-specific tyrosine kinase

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Corticosteroids		
betamethasone	Oral: 0.6 to 7.2 mg PO per day	7.2 mg/day
dexamethasone	Oral: 0.75 to 9 mg/day PO	9 mg/day
methylprednisolone	Oral: 12 to 20 mg PO per day; increase as needed by 4 mg every 2-3 days until there is marked clinical improvement	40 mg/day
prednisone	Oral: 15 mg/day to 20 mg/day; increase by 5 mg every 2-3 days as needed	60 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cholinesterase Inhibitors		
pyridostigmine (Mestinon®)	Oral immediate-release: 600 mg daily in divided doses (range, 60-1,500 mg daily in divided doses) Oral sustained release: 180-540 mg QD or BID	Immediate-release: 1,500 mg/day Sustained-release:1,080 mg/day
neostigmine (Bloxiverz®)	Oral: 15 mg TID. The daily dosage should be gradually increased at intervals of 1 or more days. The usual maintenance dosage is 15-375 mg/day (average 150 mg) IM or SC: 0.5 mg based on response to therapy	Oral: 375 mg/day
Nonsteroidal Immunosuppressants		
azathioprine (Imuran®)	Oral: 50 mg QD for 1 week, then increase gradually to 2 to 3 mg/kg/day	3 mg/kg/day
mycophenolate mofetil (Cellcept®)*	Oral: Dosage not established. 1 gram BID has been used with adjunctive corticosteroids or other non-steroidal immunosuppressive medications	2 g/day
cyclosporine (Sandimmune®)*	Oral: initial dose of cyclosporine (non-modified), 5 mg/kg/day in 2 divided doses	5 mg/kg/day
Rituxan® (rituximab), Riabni™ (rituximab-arrx), Ruxience™ (rituximab-pvvr), Truxima® (rituximab-abbs)*†	IV: 375 mg/m^2 once a week for 4 weeks; an additional 375 mg/m^2 dose may be given every 1 to 3 months afterwards	375 mg/m^2

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*
†*Prior authorization is required for rituximab products*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of serious hypersensitivity reaction to nipocalimab or to any of the excipients in Imaavy
- Boxed warning(s): none reported

Appendix D: General Information

- The MGFA stratifies patients by the extent and severity of muscle weakness. The classification has some subjectivity in it when it comes to distinguishing mild (Class II) from moderate (Class III) and moderate (Class III) from severe (Class IV). Furthermore, it is insensitive to change from one visit to the next.
- The MG-ADL scale is an 8-item patient-reported scale that measures functional status in 8 domains related to MG – talking, chewing, swallowing, breathing, impairment of

ability to brush teeth or comb hair, impairment of ability to arise from a chair, double vision, and eyelid droop. Each domain is given a score of 0-3, with 0 being normal and 3 being most severe impairment. A 2-point decrease in the MG-ADL score is considered a clinically meaningful response. The scale can be accessed here: https://myasthenia.org/Portals/0/ADL.pdf.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
gMG	Loading dose of 30 mg/kg IV once, followed by maintenance dose of 15 mg/kg IV 2 weeks after the initial dose and every 2 weeks thereafter	See regimen

VI. Product Availability

Single-dose vials: 300 mg/1.62 mL, 1,200 mg/6.5 mL

VII. References

1. Imaavy Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; April 2025. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/IMAAVY-pi.pdf. Accessed May 8, 2025.
2. 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 Neurology. 2025;24(2):105-116.
3. ClinicalTrials.gov. A study of nipocalimab administered to adults with generalized myasthenia gravis. Available at: https://clinicaltrials.gov/study/NCT04951622. Accessed January 27, 2025.
4. ClinicalTrials.gov. A study of nipocalimab in children aged 2 to less than 18 years with generalized myasthenia gravis. Available at: https://clinicaltrials.gov/study/NCT05265273. Accessed May 8, 2025.
5. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology 2016;87:419-425.
6. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis 2020 update. Neurology 2021;96:114-22.
7. Treatment strategy. Myasthenia Gravis Foundation of America. Available at: https://myasthenia.org/Newly-Diagnosed/Treatment-Strategy. Accessed January 27, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9256	Injection, nipocalimab-aahu, 3 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively. Added step therapy bypass for IL HIM per IL HB 5395.	04.07.25	05.25
RT4: Drug is now FDA approved - criteria updated per FDA labeling: revised minimum age limit from 18 years to 12 years and removed coverage of anti-LRP4 positive disease; modified continued approval duration from 6 months to 12 months for MED/HIM and 6 months or to the member's renewal date for COM as gMG is a chronic condition; references reviewed and updated.	05.08.25	
HCPCS code added [C9305], HCPCS codes removed [J3590, C9399].	09.11.25	
HCPCS code updates: added [J9256], removed [C9305].	01.06.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.