

Clinical Policy: Nipocalimab-aahu (Imaavy)

Reference Number: PA.CP.PHAR.720

Effective Date: 02/2026

Last Review Date: 01/2026

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 PA Health & Wellness® 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 \geq 12 years;
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) score \geq 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;
8. Failure of a corticosteroid (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
9. Failure of at least one immunosuppressive therapy (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;
10. Imaavy is not prescribed concurrently with Bkerv™/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

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Generalized Myasthenia Gravis (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
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 Bkemy/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: 6 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Corticosteroids		
<i>betamethasone</i>	<i>Oral: 0.6 to 7.2 mg PO per day</i>	<i>7.2 mg/day</i>
<i>dexamethasone</i>	<i>Oral: 0.75 to 9 mg/day PO</i>	<i>9 mg/day</i>
<i>methylprednisolone</i>	<i>Oral: 12 to 20 mg PO per day; increase as needed by 4 mg every 2-3 days until there is marked clinical improvement</i>	<i>40 mg/day</i>
<i>prednisone</i>	<i>Oral: 15 mg/day to 20 mg/day; increase by 5 mg every 2-3 days as needed</i>	<i>60 mg/day</i>
Cholinesterase Inhibitors		
<i>pyridostigmine (Mestinon[®])</i>	<i>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</i>	<i>Immediate- release: 1,500 mg/day Sustained- release: 1,080 mg/day</i>
<i>neostigmine (Bloxiverz[®])</i>	<i>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</i>	<i>Oral: 375 mg/day</i>
Nonsteroidal Immunosuppressants		
<i>azathioprine (Imuran[®])</i>	<i>Oral: 50 mg QD for 1 week, then increase gradually to 2 to 3 mg/kg/day</i>	<i>3 mg/kg/day</i>
<i>mycophenolate mofetil (Cellcept[®])*</i>	<i>Oral: Dosage not established. 1 gram BID has been used with adjunctive corticosteroids or other non-steroidal immunosuppressive medications</i>	<i>2 g/day</i>
<i>cyclosporine (Sandimmune[®])*</i>	<i>Oral: initial dose of cyclosporine (non- modified), 5 mg/kg/day in 2 divided doses</i>	<i>5 mg/kg/day</i>
<i>Rituxan[®] (rituximab), Riabni[™] (rituximab- arrx), Ruxience[™] (rituximab-pvvr), Truxima[®] (rituximab- abbs)*†</i>	<i>IV: 375 mg/m² once a week for 4 weeks; an additional 375 mg/m² dose may be given every 1 to 3 months afterwards</i>	<i>375 mg/m²</i>

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
Policy created	01/2026