

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Imaavy (nipocalimab-aahu)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Imaavy is a neonatal Fc receptor blocker 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.

Myasthenia gravis is an autoimmune disorder affecting the neuromuscular junction, characterized by muscle weakness and fatigue. The cause is an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction, most commonly the acetylcholine receptor (90%). Autoantibodies attack the AChR, blocking or destroying the receptors and damaging the neuromuscular junction, which impairs neuromuscular transmission and prevents muscles from contracting, as acetylcholine is unable to activate its receptor. Ocular motility, swallowing, speech, mobility, and respiratory function can all be affected.

Pyridostigmine, an acetylcholinesterase inhibitor, is the initial drug of choice prescribed for MG. It eases symptoms by slowing the breakdown of acetylcholine. If control is inadequate, immunosuppressive treatment is added, such as prednisone and/or azathioprine. Other drugs are used in cases of severe or refractory MG or in myasthenic crisis, which is an emergency.

Imaavy (nipocalimab-aahu) will be considered for coverage when the following criteria are met:

Myasthenia Gravis

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of MGFA class II-IV myasthenia gravis (see appendix); AND
4. Lab result in chart notes shows the member is seropositive for AChR or MuSK antibodies; AND
5. Member has tried and failed at least 1 conventional therapy:
 - a) pyridostigmine
 - b) corticosteroid for at least 4 weeks
 - c) non-steroid immunosuppressant (e.g., azathioprine) for at least 6 months
6. **Dosage allowed/Quantity limit:**
 Initial: 30 mg/kg once via IV infusion
 Maintenance: two weeks after initial dose, administer 15 mg/kg IV infusion every two weeks thereafter

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document clinically meaningful improvement in symptom severity and daily functioning compared to pre-treatment baseline (e.g., improved MG-ADL or QMG scores).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Imaavy (nipocalimab-aahu) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/06/2025	New policy for Imaavy created.

Appendix:

MG Foundation of America (MGFA) Clinical Classification	
Class I	any ocular weakness; all other muscle strength is normal
Class II	mild weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class III	moderate weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class IV	severe weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class V	defined by intubation, with or without mechanical ventilation

References:

1. Imaavy [prescribing information]. Janssen Biotech, Inc.; 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 Neurol*. 2025;24(2):105-116. doi:10.1016/S1474-4422(24)00498-8
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016;87(4):419-425. doi:10.1212/WNL.0000000000002790
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124
5. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. *J Clin Med*. 2022;11(6):1597. Published 2022 Mar 14. doi:10.3390/jcm11061597
6. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
7. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
8. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

Effective date: 10/01/2025

Revised date: 05/06/2025