

Imaavy® (nipocalimab-aahu intravenous infusion)

When requesting Imaavy® (generic name), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved indication(s)

Imaavy (nipocalimab-aahu) 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.

Coverage Guidelines

Generalized Myasthenia Gravis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 12 years of age;
 - If 18 years or older, patient meets BOTH of the following:
 - Myasthenia Gravis Foundation of America classification of II to IV;
 - AND
 - Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥ 6 ;
- Confirmed anti-acetylcholine receptor antibody-positive OR anti-muscle-specific tyrosine kinase antibody-positive;
- Meets one of the following:
 - Previously received or is currently receiving pyridostigmine; OR
 - Has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine;
- Has evidence of unresolved symptoms of generalized myasthenia gravis (e.g., difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity);
- The medication is being prescribed by or in consultation with a neurologist.

Approval duration (initial): 6 months

Reauthorization:

The individual must meet **all** of the following criteria for renewal:

- Patient is ≥ 12 years of age;
- According to the prescriber, patient is continuing to derive benefit from Imaavy (e.g., improvements in speech, swallowing, mobility, and respiratory function);
- The medication is being prescribed by or in consultation with a neurologist.

Approval duration (renewal): 1 year

Dosing Recommendations

The recommended dose is 30 mg/kg once via intravenous infusion, followed by a maintenance dosage of 15 mg/kg via intravenous infusion starting 2 weeks after initial dose and continue every 2 weeks thereafter.

References

1. Imaavy™ intravenous infusion [prescribing information. Horsham PA: Janssen Biotech; April 2025.
2. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis Fact Sheet. National Institutes of Health (NIH) Publication No. 17-768. Publication last updated: March 2020. Available at: https://www.ninds.nih.gov/sites/default/files/migrate-documents/myasthenia_gravis_e_march_2020_508c.pdf. Accessed on May 6, 2025.
3. Cleanthous S, Mork AC, Regnault A, et al. Development of the myasthenia gravis (MG) symptoms PRO: a case study of a patient-centred outcome measure in rare disease. *Orphanet J Rare Dis.* 2021;16:457.
4. Rodolico C, Bonanno C, Toscano A, and Vita G. MuSK-associated myasthenia gravis: clinical features and management. *frontiers in Neurology.* 2020;11:660.
5. Antozzi C, Vu T, Ramchandren S, et al. Safety and efficacy of nipocalimab in adults with generalised myasthenia gravis (Vivacity-MG3): a phase 3, randomized, double-blind, placebo-controlled study. *Lancet Neurol.* 2025;24:105-116.
6. An open-label uncontrolled multicenter study to evaluate the pharmacokinetics, pharmacodynamics, and safety and activity of nipocalimab in children aged 2 to less than 18 years with generalized myasthenia gravis (NCT05265273). Available at: <https://clinicaltrials.gov/study/NCT05265273>. Accessed on May 2, 2025.
7. Sanders DB, Wolfe GI, Benatar M, et al. International Consensus Guidance for Management of Myasthenia Gravis. *Neurology.* 2016;87:419-425.
8. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology.* 2021;96(3):114-122.
9. O'Connell K, Ramdas S, Palace J. Management of juvenile myasthenia gravis. *Front Neurol.* 2020;11:743. Doi: 10.3389/fneuro.2020.00743.

Imaavy® (nipocalimab-aahu intravenous infusion)