

nipocalimab-aahu (Imaavy)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Administration

Drug Details

USP Category: ANTIMYASTHENIC AGENTS

Mechanism of Action: Neonatal Fc receptor blocker

HCPCS:

J9256:Injection, nipocalimab-aahu, 3 mg

How Supplied:

300 mg/1.62 mL (185 mg/mL) in a single-dose vial

1,200 mg/6.5 mL (185 mg/mL) in a single-dose vial

Condition(s) listed in policy (see coverage criteria for details)

- Generalized Myasthenia Gravis (gMG)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Generalized Myasthenia Gravis (gMG)

Meets medical necessity if all the following are met:

Initial

1. Age consistent with the FDA indication (12 years and older)
2. Prescribed by or in consultation with a neurologist
3. Patient has positive serologic test for anti-AChR antibodies or Anti-MUSK
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 6
5. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV

6. Patient is on at least one treatment for gMG (e.g. acetylcholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies)

Reauthorization

1. Patient has demonstrated a MG-ADL total score of at least a 2-point improvement
2. Reduction in signs and symptoms of myasthenia gravis

Covered Doses:

Up to 30 mg/kg given intravenously (IV) for the first dose, followed two weeks later by 15 mg/kg given IV every two weeks thereafter

Coverage Period:

Initial: 6 months

Reauthorization: Yearly

References

1. Imaavy (nipocalimab-aahu) Prescribing Information. Janssen Biotech, Inc., Horsham, PA: 4/2025

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- HCPCS: Added J9256, effective 1/1/2026.

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee