

## 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. Meets one of the following:
  - a. Patient has a positive serological test for Anti-AChR, and BOTH of the following:
    - i. Patient is on at least one treatment for gMG (e.g. acetylcholinesterase inhibitors, corticosteroids, or non-steroid immunosuppressive therapies)

- ii. **Effective 5/1/2026 and after.** Patient had an inadequate response, intolerable side effect, or contraindication to one preferred product (e.g. Vyvgart, Vyvgart Hytrulo, or Epysqli)
- b. Patient has a positive serological test for Anti-MuSK
4. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
5. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score greater than or equal to 6

#### Reauthorization

1. Patient's continued response to therapy as shown by one of the following:
  - a. Patient has demonstrated a MG-ADL total score of at least a 2-point improvement
  - b. 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: 1Q2026

Changes from previous policy version:

- Add prerequisite therapy requirement for Vyvgart/Vyvgart Hytrulo or biosimilar Epysqli.  
Rationale: More cost-effective therapeutic alternatives available

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*