imaavy with Me | imaavy (nipocalimab-aahu)

IMAAVY Prior Authorization Checklist

Reminders and Tips When Completing Prior Authorizations for Your Patients

Each health plan may have its own unique prior authorization (PA) form with varying requirements. It is important to gather necessary information during the patient's first appointment to ensure an effective process with minimal delays.

4 Essentials for Approval

1. Use a diagnosis that matches the FDA indication (ICD-10 code)

2. Align with FDA-approved dosing (first infusion will include loading dose)

3. Include a list of prior therapies used (generics, biosimilars, corticosteroids)

4. Refer to IMAAVY Billing and Coding Guide* when billing for product reimbursement
- Please refer to **J9256, Injection, nipocalimab-aahu, 3 mg**[1] for IMAAVY

Consider gathering the following information to assist when completing PA forms:

Patient Information

- ☐ **Patient Insurance Information**
  - Copy of the patient's prescription card (front and back)
  - Copy of the patient's health insurance card (front and back)
- ☐ **Patient Contact Information (phone and email preferred)**

Patient Diagnosis/Clinical Information

- ☐ **ICD-10 Code**
- ☐ **Disease Severity Assessments:**
  - MG-ADL
  - MGFA score
- ☐ **Supporting Clinical Information**
  - Lab results and dates
- ☐ **Patient Medication History (including treatment from previous healthcare providers)**
  - Duration of therapy
  - Clinical response
  - Allergy
  - Strength
  - Schedule

Other Resources

- ☐ **Letter of Medical Necessity**
  - Visit JNJwithMe.com/hcp/IMAAVY and look under the Forms & Guides drop-down for a sample letter
  - **For expedited requests, adequate information should be provided to support the urgent nature of the request** (front and back)
- ☐ **Patient Authorization and Notice of Release of Information**
- ☐ **Product Full Prescribing Information, Peer-Reviewed Journal Articles, or Clinical Guidelines**
- ☐ **Formulary Exception Letter**

Resources for IMAAVY treatment

Data rates may apply.

Codes are supplied for informational purposes and represent no statement, promise, or a guarantee that reimbursement will be made. Information provided is not intended to increase or maximize reimbursement.

*Check specific payer requirements when submitting claims for IMAAVY.

Reference: 1. Centers for Medicare & Medicaid Services Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations. Accessed November 5, 2025. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-3-2025-drugs-biologicals.pdf

FDA=U.S. Food & Drug Administration; **ICD-10**=International Classification of Diseases, Tenth Revision.

SELECTED IMPORTANT SAFETY INFORMATION

IMAAVY® is contraindicated in patients with a history of serious hypersensitivity reaction to nipocalimab-aahu or to any of the excipients in IMAAVY®. Anaphylaxis and angioedema reactions may occur. IMAAVY® may increase the risk of infection. Delay administration in patients with clinically active infection until the infection resolves. If such an infection develops, administer appropriate treatment and consider withholding IMAAVY® until infection resolves. Monitor patients during and 30 minutes after IMAAVY® administration for hypersensitivity and infusion-related reactions. Avoid use of live vaccines in patients treated with IMAAVY®. Please see related and other Important Safety Information on the following page.

Once you have made the decision to prescribe IMAAVY

IMAAVY withMe provides dedicated resources to help your patients start and stay on treatment

This free support program offers:

- Access and affordability support to help your patients prescribed IMAAVY get started on therapy as quickly as possible
- 1-on-1 patient support and resources, including a dedicated Nurse Navigator,† an Infusion Center Finder, and personalized support throughout their treatment journey

†Nurse Navigators do not provide medical advice. Patient Authorization is required for enrollment in Nurse Navigator support.

IMAAVY withMe Access Program

When commercial insurance coverage is delayed more than 5 business days or denied, IMAAVY withMe offers eligible patients IMAAVY at no cost for up to 3 years or until their commercial insurance covers the medicine. See program requirements at **IMAAVYwithMeAccess.com**

The patient support and resources provided by IMAAVY withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe IMAAVY.

Call 844-4withMe (844-494-8463), Monday-Friday, 8:00 AM to 8:00 PM ET. Visit IMAAVYhcp.com

INDICATION

IMAAVY® (nipocalimab-aahu) is a neonatal Fc receptor (FcRn) 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

IMAAVY® is contraindicated in patients with a history of serious hypersensitivity reaction to nipocalimab-aahu or to any of the excipients in IMAAVY®. Reactions have included anaphylaxis and angioedema.

WARNINGS AND PRECAUTIONS

Infections

IMAAVY® may increase the risk of infection, including serious and severe infections. The most common infections observed in Study 1 and its extension study in patients treated with IMAAVY® for gMG were upper respiratory tract infection (46%), respiratory tract infections (28%; including pneumonia, bronchitis, COVID-19), urinary tract infection (15%), herpes (8%; including herpes simplex, herpes zoster, herpes zoster oticus), influenza (8%), oral infection (8%; including candidiasis and dental infections), and skin infection (7%; including cellulitis). Two cases of infections (1%; including cellulitis and urinary tract infection) led to discontinuation of IMAAVY®. Delay IMAAVY® administration in patients with an active infection until the infection is resolved. During treatment with IMAAVY®, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding IMAAVY® until the infection has resolved.

Patients treated with IMAAVY® may be at an increased risk of activation of latent viral infections. Follow standard vaccination guidelines.

Immunization: Evaluate the need to administer age-appropriate vaccinations before initiation of treatment with IMAAVY®. The safety of immunization with live vaccines and the immune response to vaccination during treatment with IMAAVY® are unknown. Live vaccines are not recommended during treatment with IMAAVY®.

Hypersensitivity Reactions

Administration of IMAAVY® may result in hypersensitivity reactions, including angioedema, anaphylaxis, rash, urticaria, and eczema. Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor the patient during treatment and for 30 minutes after administration. If a hypersensitivity reaction occurs during administration, discontinue IMAAVY® infusion and institute appropriate supportive measures if needed.

Infusion-Related Reactions

Administration of IMAAVY® may result in infusion-related reactions, including headache, influenza-like illness, rash, nausea, fatigue, dizziness, chills, and erythema. Monitor the patient during treatment and for 30 minutes after each infusion. If a severe infusion-related reaction occurs, discontinue IMAAVY® infusion and initiate appropriate therapy. Consider the risks and benefits of readministering IMAAVY® following a severe infusion-related reaction. If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medication.

ADVERSE REACTIONS

Most common (≥10% of patients) adverse reactions associated with IMAAVY® include: respiratory tract infection, peripheral edema, and muscle spasms.

Adverse reactions in ≥5% of patients taking IMAAVY® include: urinary tract infection, herpes zoster and simplex infection, oral infection, hypersensitivity reaction, abdominal pain, back pain, pyrexia, diarrhea, cough, anemia, dizziness, nausea, hypertension, and insomnia.

Laboratory Findings

Lipid Increases: In a clinical study, patients treated with IMAAVY® had elevations from normal to high of fasting total and LDL cholesterol and decreases from normal to low of fasting HDL cholesterol.

Pediatric Patients 12 Years of Age and Older

Adverse reactions in pediatric patients were consistent with those observed in adult patients with gMG.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are limited data on the use of IMAAVY® in pregnant women with gMG. IMAAVY® reduces maternal serum IgG concentration and impedes placental IgG transfer to the fetus. Risks and benefits should be considered prior to administering live vaccines to infants exposed to IMAAVY® *in utero*.

Lactation: Nipocalimab-aahu is excreted in human colostrum and breastmilk. There are insufficient data on the effect of IMAAVY® in the breastfed infant. There are no data on the effect of nipocalimab-aahu on milk production.

Pediatric Use: The safety and effectiveness of IMAAVY® for the treatment of gMG in pediatric patients below the age of 12 years have not been established.

Please read the full Prescribing Information and Medication Guide for IMAAVY®. Provide the Medication Guide to your patients and encourage discussion.

Dosage Form and Strengths: IMAAVY® is supplied as a 300 mg/1.62 mL (185 mg/mL) and a 1,200 mg/6.5 mL (185 mg/mL) single-dose vial per carton for intravenous use after dilution.
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