imaavy™ (nipocalimab-aahu)

You are cordially invited to attend a live educational program

IMAAVY™ (nipocalimab-aahu): An FDA-approved option for your patients with gMG 12 years of age and older

PRESENTED BY

Deena Rodney, NP

Nurse Practitioner

Neurology Associates

Maitland, FL

The consultants are paid speakers for Janssen Biotech, Inc., a Johnson & Johnson company. The speakers are presenting on behalf of Johnson & Johnson, and must present information in compliance with FDA requirements applicable to Johnson & Johnson.

Monday January 26, 2026

6:00 PM ET Arrival
6:30 PM ET Dinner & Presentation

Meeting Code: 2025-08134

The Capital Grille

5197 Big Island Drive
Jacksonville, FL 32246
904-997-9233

Meals will be provided at all live locations.

Participate in the live event with us.

Please RSVP at MyDomeProgramRegistration.com

Enter Meeting Code: 2025-08134

RSVP online by: 1/16/2026

Data rates may apply.

Please note that your email will be required for registration. The information you provide will only be used to facilitate your attendance at this program. If you have questions about this program, please contact your Johnson & Johnson representative.

We look forward to your participation in this informative discussion. Sponsored by Johnson & Johnson.

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.

Please see related and other Important Safety Information on the reverse.

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800 Ridgeview Drive
Horsham, PA 19044

IMPORTANT SAFETY INFORMATION (continued)

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 accompanying 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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DISCLOSURES

In adherence with PhRMA guidelines, spouses or other guests are not permitted to attend company-sponsored programs.

For all attendees, please be advised that information such as your name and the value and purpose of any educational item, meal, or other items of value you receive may be publicly disclosed. If you are licensed in any state or other jurisdiction, or are an employee or contractor of any organization or governmental entity, that limits or prohibits meals from pharmaceutical companies, please identify yourself so that you (and we) are able to comply with such requirements.

Please note that the company prohibits the offering of gifts, gratuities, or meals to federal government employees/officials. Thank you for your cooperation.

FDA=U.S. Food and Drug Administration.

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