YOUR GUIDE TO

DOSING AND ADMINISTRATION

Consistent dosing schedule for your patients 12 years of age and older living with anti-AChR or anti-MuSK antibody-positive **generalized myasthenia gravis (gMG).**[1]

imaavy™
(nipocalimab-aahu)

INDICATION

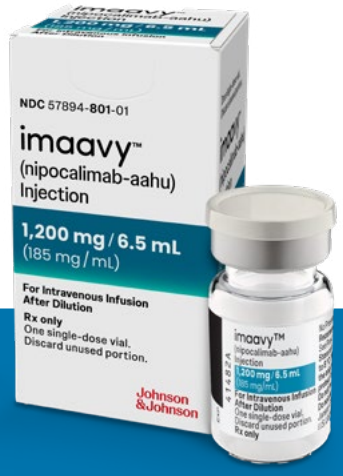
IMAAVY™ (nipocalimab-aahu) is a neonatal Fc receptor (FcRn) blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

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 pages 8–9.

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

DOSAGE FORMS AND STRENGTHS



1200 mg/6.5 mL
(185 mg/mL) in a single-dose vial[1]

INGREDIENTS[1]

- **Active ingredient:** nipocalimab-aahu
- **Inactive ingredients:** arginine hydrochloride, histidine, L-histidine monohydrochloride monohydrate, methionine, polysorbate 80, sucrose, and water for injection.[1]

Dilute IMAAVY™ prior to administration[1]

Administer* via **intravenous (IV) infusion** only[1]

***See pages 4 and 5 for full preparation and administration details.**

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RECOMMENDED DOSAGE

For adult and pediatric patients 12 years and older with gMG, the recommended dosing of IMAAVY™ is:

At least 30 minutes[1]

The initial dosage of IMAAVY is 30 mg/kg administered once via intravenous infusion over at least 30 minutes.[1]

At least 15 minutes[1]

Two weeks after the initial dosage, administer a maintenance dosage of 15 mg/kg via intravenous infusion over at least 15 minutes.[1]

Every 2 weeks[1]

Continue the maintenance dosage of 15 mg/kg administered over at least 15 minutes every 2 weeks thereafter.[1]

If a scheduled infusion appointment is missed, the maintenance dose of IMAAVY should be administered as soon as possible. Resume dosing every 2 weeks thereafter.[1]

Consistent dosing allows for a schedule you and your patients can plan around.[1]

Only IMAAVY is administered* via an IV infusion every 2 weeks—a dosing schedule unique among FDA-approved FcRn blockers for gMG.[1-4]

*See page 5 for full administration details.

Monitor the patient for 30 minutes after each infusion for signs or symptoms of an infusion-related or hypersensitivity reaction.[1]

POSSIBLE SIDE EFFECTS[1]

Allergic reactions can happen during IMAAVY infusion.

- Swelling of the face, lips, mouth, tongue, or throat
- Difficulty swallowing or breathing
- Itchy rash (hives)
- Chest pain or tightness

The most common adverse reactions were:

- Respiratory tract infections (18%)
- Peripheral edema (12%)
- Muscle spasms (12%)

If an adverse reaction occurs during administration of IMAAVY, the infusion may be slowed or stopped at the discretion of the healthcare professional.[1]

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PREPARING IMAAVY™

Prior to administration, **IMAAVY single-dose vials require dilution** in 0.9% Sodium Chloride Injection, USP. For patients who weigh 40 kg or more, the total volume to be administered is 250 mL; for patients who are 12 years or older and weigh less than 40 kg, the total volume to be administered is 100 mL.[1]

Prepare the solution for infusion using aseptic technique as follows:

STEP 1

- **Calculate the dosage** (mg), total drug volume (mL) of IMAAVY solution, and number of IMAAVY vials needed, based on the patient's current weight [*see Dosage and Administration (2.2)*]. Each single-dose vial of IMAAVY has a concentration of 185 mg/mL[1]

STEP 2

- **Parenteral drug products should be inspected visually** for particulate matter and discoloration prior to administration, whenever solution and container permit. Check that the solution in each vial is colorless to slightly brownish, clear to slightly opalescent, and free of visible particles. *Do not use if visible particles are present or if the solution is discolored (other than colorless to slightly brownish)*[1]

STEP 3

- **Gently withdraw the calculated volume of IMAAVY from the vial(s).** *Discard any unused portion of the vials*[1]

STEP 4

- **Dilute total volume of IMAAVY** withdrawn by adding to an infusion container containing 0.9% Sodium Chloride Injection, USP, to a final volume of 250 mL for patients who weigh 40 kg or more, or 100 mL for patients who weigh less than 40 kg. Only use infusion containers made of polyolefin, polypropylene, or polyvinylchloride. Gently invert the infusion container **at least 10 times** to mix the solution. *Do not shake*[1]

STEP 5

- **Verify that a uniform solution has been achieved** by visual inspection. *Do not use if particulate matter or discoloration is present*[1]

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ADMINISTRATION

STEP 1

- **If the diluted solution is refrigerated prior to administration**, allow to warm to room temperature. Do not use external heat sources to warm IMAAVY™. Administer the diluted solution by intravenous infusion only using an infusion set with an in-line or add-on, sterile, non-pyrogenic, low protein–binding filter made of polyethersulfone or polysulfone (pore size 0.2 micrometer or less). Administration sets must be made of either polybutadiene, polyethylene, polyurethane, polypropylene, or polyvinylchloride. *Do not infuse IMAAVY concomitantly in the same intravenous line with other agents*[1]

STEP 2

- **Administer IMAAVY infusion intravenously** over at least 30 minutes for the initial dose (30 mg/kg) and at least 15 minutes for subsequent doses (15 mg/kg). *If an adverse reaction occurs during administration of IMAAVY, the infusion may be slowed or stopped at the discretion of the healthcare professional*[1]

STEP 3

- **Monitor the patient for 30 minutes** after each infusion for signs or symptoms of an infusion-related or hypersensitivity reaction[1]

Storage Conditions of the Diluted Solution

Administer the diluted IMAAVY solution immediately after preparation. If the diluted IMAAVY solution is not used immediately:

- Protect from light
- Store refrigerated at 2°C to 8°C (36°F to 46°F) for no more than 24 hours
- Do not freeze
- After preparation or removal from the refrigerator, use or discard the IMAAVY diluted solution within 12 hours, including infusion time. During these 12 hours, store under ambient light at 15°C to 30°C (59°F to 86°F)

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INFUSION LOCATIONS

IMAAVY™ can be administered in a variety of settings, including:

At a patient's home

An infusion service provider may be able to help your patients take IMAAVY at home.

At an infusion center

You can send patients to an infusion center that carries IMAAVY.

At your office

You can prescribe and administer IMAAVY in your office.

At a hospital

You can send patients to hospitals where they can receive IMAAVY as an outpatient service (not requiring hospital admission).

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PLAN AND PREPARE YOUR DOSE[1]

Formula

	Initial dose	Maintenance dose
Dose amount	30 mg/kg	15 mg/kg
Duration	At least 30 minutes	At least 15 minutes
Frequency	Once (initial administration)	Every 2 weeks
Diluent*	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP
Formula for volumetric dose	(30 mg/kg) x (patient weight in kg) ÷ (185 mg/mL)	(15 mg/kg) x (patient weight in kg) ÷ (185 mg/mL)
Formula for no. of vials (for 6.5 mL/vial)	Volumetric dose (mL)/6.5 mL	Volumetric dose (mL)/6.5 mL

Dosing

Weight of patient (kg)	**Initial dose** (mL)	**Maintenance dose** (mL)
40	6.5	3.2
45	7.3	3.6
50	8.1	4.1
55	8.9	4.5
60	9.7	4.9
65	10.5	5.3
70	11.4	5.7
75	12.2	6.1
80	13.0	6.5
85	13.8	6.9
90	14.6	7.3
95	15.4	7.7
100	16.2	8.1
105	17.0	8.5
110	17.8	8.9
115	18.6	9.3
120	19.5	9.7
125	20.3	10.1
130	21.1	10.5
135	21.9	10.9
140	22.7	11.4
145	23.5	11.8
150	24.3	12.2
155	25.1	12.6
160	25.9	13.0
165	26.8	13.4

*For patients who weigh 40 kg or more, the total volume to be administered is 250 mL; for patients who are 12 years or older and weigh less than 40 kg, the total volume to be administered is 100 mL.[1]

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IMPORTANT SAFETY INFORMATION

INDICATION

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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.

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IMPORTANT SAFETY INFORMATION (cont)

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.

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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.

cp-509745v1

References: 1. IMAAVY™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Vyvgart® [Prescribing Information]. Boston, MA: argenx US, Inc. 2024. **3.** Vyvgart® Hytrulo [Prescribing Information]. Boston, MA: argenx US, Inc. 2025. **4.** Rystiggo® [Prescribing Information]. Smyrna, GA: UCB, Inc. 2024.

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