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.

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

DOSAGE FORMS AND STRENGTHS

300 mg/1.62 mL
(185 mg/mL) in a single-dose vial[1]

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 5 and 6 for full preparation and administration details.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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DOSAGE FORMS AND CODING INFORMATION

National Drug Code (NDC)[1]:

300 mg/1.62 mL (185 mg/mL) Vial	
10-digit NDC number	57894-800-01
11-digit NDC number	57894-**0**800-01

1200 mg/6.5 mL (185 mg/mL) Vial	
10-digit NDC number	57894-801-01
11-digit NDC number	57894-**0**801-01

J-Code - Healthcare Common Procedure Coding System (HCPCS)[2]:

J9256 | Injection, nipocalimab-aahu, 3 mg

Effective January 1, 2026, IMAAVY™ (nipocalimab-aahu) has a permanent J-code.

The permanent J-code for IMAAVY™ is effective for dates of service on or after January 1, 2026.* For dates of service prior to January 1, 2026, consult with the individual payer's policies to ensure you are using the appropriate code for payer-specific reimbursement needs.

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

*Please check with individual payers for specific documentation and guidance when billing.

IMAAVY™ is distributed through a contracted network of specialty distributors and a limited specialty pharmacy network.

All information is current as of November 2025.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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™.

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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 (IV) 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 IV 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.[1,3-5]

*See page 6 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]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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.

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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]

IMPORTANT SAFETY INFORMATION (CONT'D)
WARNINGS AND PRECAUTIONS (CONT'D)
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.

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

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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)

IMPORTANT SAFETY INFORMATION (CONT'D)
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.

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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).

The Infusion Center Finder can help your patients choose their IMAAVY™ treatment location

Apply the search capabilities of the Infusion Center Finder* to help you locate an infusion site convenient to your patient's home or workplace. Searchable by city or ZIP code, this helpful site provides detailed search results organized by driving distance. This website also includes information about the infusion sites such as business hours, insurance plans accepted, and medicines infused.

Find an infusion center at 2infuse.com.

Are you an infusion center? Register to list with 2infuse.com.

*The inclusion of an infusion center in the locator tool does not represent an endorsement from Johnson & Johnson. The locator tool is for informational purposes only. All users agree that use of the locator tool is at their own risk.

IMPORTANT SAFETY INFORMATION (CONT'D)
ADVERSE REACTIONS (CONT'D)

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.

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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 1.62 mL/vial)	Volumetric dose (mL)/ 1.62 mL	Volumetric dose (mL)/ 1.62 mL

Dosing

Weight of patient (kg)	Initial dose		Maintenance dose		# of 300 mg vials needed for maintenance dose*
	mg	mL	mg	mL	
40	1,200	6.5	600	3.2	2
45	1,350	7.3	675	3.6	3
50	1,500	8.1	750	4.1	3
55	1,650	8.9	825	4.5	3
60	1,800	9.7	900	4.9	3
65	1,950	10.5	975	5.3	4
70	2,100	11.4	1,050	5.7	4
75	2,250	12.2	1,125	6.1	4
80	2,400	13.0	1,200	6.5	4
85	2,550	13.8	1,275	6.9	5
90	2,700	14.6	1,350	7.3	5
95	2,850	15.4	1,425	7.7	5
100	3,000	16.2	1,500	8.1	5
105	3,150	17.0	1,575	8.5	6
110	3,300	17.8	1,650	8.9	6
115	3,450	18.6	1,725	9.3	6
120	3,600	19.5	1,800	9.7	6
125	3,750	20.3	1,875	10.1	7
130	3,900	21.1	1,950	10.5	7
135	4,050	21.9	2,025	10.9	7
140	4,200	22.7	2,100	11.4	7
145	4,350	23.5	2,175	11.8	8
150	4,500	24.3	2,250	12.2	8
155	4,650	25.1	2,325	12.6	8
160	4,800	25.9	2,400	13.0	8
165	4,950	26.8	2,475	13.4	9

*Four 300 mg vials are equivalent to one 1200 mg vial. These vials can be used interchangeably to achieve the required maintenance dose.

†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]

IMPORTANT SAFETY INFORMATION (CONT'D)
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*.

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

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imaavy withMe

ONCE A DECISION HAS BEEN MADE TO PRESCRIBE IMAAVY™

IMAAVY withMe provides support every step of the way.

IMAAVY withMe offers a wide breadth of support for your eligible patients, including free access to resources, guidance, and personalized support throughout their treatment journey.

Learn more about IMAAVY withMe at JNJwithMe.com/hcp/IMAAVY

Call 844-4withMe (844-494-8463), Monday–Friday, 8:00 AM–8:00 PM ET

Scan to enroll your patients in IMAAVY withMe

Data rates may apply.

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™.

IMPORTANT SAFETY INFORMATION (CONT'D)
USE IN SPECIFIC POPULATIONS (CONT'D)

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.

cp-509745v1

References: 1. IMAAVY™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations. Third Quarter, 2025 HCPCS Coding Cycle. October 21, 2025. Accessed November 5, 2025. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-3-2025-drugs-biologicals.pdf. **3.** Vyvgart® [Prescribing Information]. Boston, MA: argenx US, Inc. 2025. **4.** Vyvgart® Hytrulo [Prescribing Information]. Boston, MA: argenx US, Inc. 2025. **5.** Rystiggo® [Prescribing Information]. Smyrna, GA: UCB, Inc. 2025.

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