imaavy® (nipocalimab-aahu)

FOR PATIENTS WITH wAIHA

Dosing & Administration Guide for IMAAVY® (nipocalimab-aahu)

IMAAVY is FDA-approved for the treatment of warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years and older currently or previously treated with corticosteroids[1]

INDICATION

IMAAVY® (nipocalimab-aahu) is a neonatal Fc receptor (FcRn) blocker indicated for the treatment of warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids.

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. In the wAIHA Study and its extension (wAIHA studies), 80 (71%) out of 113 patients treated with IMAAVY reported 184 events of infection and serious infections were reported in 12% of patients. The infections included upper respiratory tract infection (34%), respiratory tract infection (33%), urinary tract infection (12%), and gastroenteritis (5%). Three (2.7%) cases of infections (pneumonia, salmonella sepsis and spontaneous bacterial peritonitis) led to discontinuation of IMAAVY.

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

For your patients 12 years and older with wAIHA currently or previously treated with corticosteroids

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 (CONT'D)

Infections (cont'd)

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: 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. Evaluate the need to administer age-appropriate vaccinations before initiation of treatment with IMAAVY.

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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	57894-0800-01

1200 mg/6.5 mL (185 mg/mL) vial

10-digit NDC number	57894-801-01
11-digit NDC number	57894-0801-01

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

J9256 | Injection, nipocalimab-aahu, 3 mg

The permanent J-code for IMAAVY is effective for dates of service on or after January 1, 2026.*

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.

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. In the wAIHA Study, hypersensitivity reactions were mild to moderate and 76% of the hypersensitivity reactions occurred within 2 weeks of administration. In the wAIHA studies, 9 (8%) out of 113 patients treated with IMAAVY experienced hypersensitivity reactions.

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.

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

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RECOMMENDED DOSAGE

For adult and pediatric patients 12 years and older with wAIHA currently or previously treated with corticosteroids, the recommended dosing of IMAAVY is:

Initial dosing

30 mg/kg IV infusion administered over at least **30 minutes**.[1]

Subsequent dosing

30 mg/kg IV infusion administered over at least **15 minutes**, 4 weeks after the initial dosage.[1]

Dosing frequency

Continue the subsequent dosage **every 4 weeks thereafter.**[1]

If a scheduled infusion is missed, administer the dose of IMAAVY as soon as possible. Resume dosing, maintaining the treatment interval.[1]

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

See page 6 for full administration details.

SELECT SAFETY[1]

Hypersensitivity reactions* can occur during IMAAVY infusions. These include:

- Angioedema
- Anaphylaxis
- Rash
- Urticaria
- Eczema

In clinical trials, the following infusion-related reactions† were observed in patients treated with IMAAVY:

- Headache
- Influenza-like illness
- Rash
- Nausea
- Fatigue
- Dizziness
- Chills
- Erythema

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

*In the wAIHA study, hypersensitivity reactions were mild to moderate in severity. 76% of hypersensitivity reactions occurred within 2 weeks of administration.

†In the wAIHA study, infusion-related reactions were mild to moderate in severity. 89% of infusion-related reactions occurred within 2 days of administration.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Infusion-Related Reactions

Administration of IMAAVY may result in infusion-related reactions (IRRs), including headache, influenza-like illness, rash, nausea, fatigue, dizziness, chills, and erythema. In the wAIHA Study, IRRs were mild to moderate in severity and 89% of IRRs occurred within 2 days of administration. In the wAIHA studies, 12 (11%) out of 113 patients treated with IMAAVY, experienced IRRs.

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

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PREPARING IMAAVY

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* [*2.3*]). 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 polyvinyl chloride. 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]

*Contact 1-800-JANSSEN for vial replacements.

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)
WARNINGS AND PRECAUTIONS (CONT'D)

Infusion-Related Reactions (cont'd)

Monitor patients 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 see the full Prescribing Information and Patient Information for IMAAVY. Provide the Patient Information to your patients and encourage discussion.

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For your patients 12 years and older with wAIHA currently or previously treated with corticosteroids

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 (IV) 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 polyvinyl chloride. *Do not infuse IMAAVY concomitantly in the same IV line with other agents.*

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 (30 mg/kg) for your appropriate patients with wAIHA. *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]

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 receive 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).

IMPORTANT SAFETY INFORMATION (CONT'D)
ADVERSE REACTIONS

In the wAIHA studies:
The most common (≥10% of patients) adverse reactions associated with IMAAVY include: peripheral edema, diarrhea, and pyrexia.

Adverse reactions in ≥5% of patients taking IMAAVY include: dizziness, urinary tract infection, and headache.

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For your patients 12 years and older with wAIHA currently or previously treated with corticosteroids

PLAN AND PREPARE YOUR DOSE[1]

Actual body weight should be used to calculate the dose of IMAAVY the day of the infusion.

Formula

	Initial dose	Maintenance dose
Dose amount	30 mg/kg	30 mg/kg
Duration	At least 30 minutes	At least 15 minutes
Frequency	Once (initial administration)	Every 4 weeks after the initial dosage
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)	(30 mg/kg) x (patient weight in kg) ÷ (185 mg/mL)

Dosing

Weight (kg)*	Dose =		No. of 300 mg vials†‡ OR	No. of 1200 mg vials†‡
	mg	mL		
40	1,200	6.5	4	1
45	1,350	7.3	5	2
50	1,500	8.1	5	2
55	1,650	8.9	6	2
60	1,800	9.7	6	2
65	1,950	10.5	7	2
70	2,100	11.4	7	2
75	2,250	12.2	8	2
80	2,400	13.0	8	2
85	2,550	13.8	9	3
90	2,700	14.6	9	3
95	2,850	15.4	10	3
100	3,000	16.2	10	3
105	3,150	17.0	11	3
110	3,300	17.8	11	3
115	3,450	18.6	12	3
120	3,600	19.5	12	3
125	3,750	20.3	13	4
130	3,900	21.1	13	4
135	4,050	21.9	14	4
140	4,200	22.7	14	4
145	4,350	23.5	15	4
150	4,500	24.3	15	4
155	4,650	25.1	16	4
160	4,800	25.9	16	4
165	4,950	26.8	17	5

*Weight categories shown in this table should not be used to round patient weight for dose calculation.
†Four 300 mg vials are equivalent to one 1200 mg vial. These vials can be used interchangeably to achieve the required dose.
‡Number of vials required to prepare the calculated dose volume are shown; however, the full contents of all vials may not be administered. To minimize wastage, use the fewest number of vials needed to prepare the required dose. Providers should verify individual payer requirements when submitting claims.

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

Laboratory Findings

Lipid Increases in the wAIHA Study: Patients treated with IMAAVY had elevations from normal to high of fasting total cholesterol and LDL cholesterol remained <160 mg/dL.

Please see the full Prescribing Information and Patient Information for IMAAVY. Provide the Patient Information 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

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

Pregnancy: There are limited data on the use of IMAAVY in pregnant women. IMAAVY reduces maternal serum IgG concentration and impedes placental IgG transfer to the fetus. Passive immunity in the infant may be reduced for 6 months or more. Monitor for the development of serious infections. Effectiveness of vaccines may be reduced. 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 wAIHA in pediatric patients below the age of 12 years have not been established.

Please see the full Prescribing Information and Patient Information for IMAAVY. Provide the Patient Information 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-598491v1

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 July 9, 2026. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-3-2025-drugs-biologicals.pdf

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