imaavy®
(nipocalimab-aahu)

Billing & Coding Guide for IMAAVY

in warm autoimmune hemolytic anemia (wAIHA)

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.

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. Avoid use of live vaccines in patients treated with IMAAVY. Monitor patients during and 30 minutes after IMAAVY administration for hypersensitivity and infusion-related reactions. Please see related and other Important Safety Information on page 12.

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For billing and coding or reimbursement questions, or to request support from a Field Reimbursement Manager (FRM), call **844-494-8463**, Monday–Friday, 8 AM to 8 PM ET.

Johnson & Johnson is committed to providing you with information to help guide you through the reimbursement process for IMAAVY.

Disclaimer

Please note this information is provided for your background education and is not intended to serve as guidance for specific coding, billing, and claims submissions. Decisions on which codes best describe the services provided must be made by individual providers based on their clinical judgment, payer-specific guidance, and other requirements.

Please see full Important Safety Information for IMAAVY on page 12.
Please read accompanying full Prescribing Information.

Dosing and Formulations[1]

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 dose.[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]

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

- Prior to administration, IMAAVY single-dose vials require dilution in 0.9% Sodium Chloride Injection, USP, to a final volume of 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
- Each vial of IMAAVY is at a concentration of 185 mg/mL
- Do not infuse IMAAVY concomitantly in the same intravenous line with other agents

Please refer to the Dosage and Administration section of the full Prescribing Information for complete instructions on how to prepare and administer IMAAVY.

IV, intravenous; wAIHA, warm autoimmune hemolytic anemia.

Please see full Important Safety Information for IMAAVY on page 12.
Please read accompanying full Prescribing Information.

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imaavy® (nipocalimab-aahu)

Product Information

National Drug Code (NDC)[1]

Payer requirements for NDC use and format can vary widely. Refer to sample claims forms beginning on page 6 for additional information.[2]

FDA-Specified NDC		
10-digit NDC (5-3-2 format)	**11-digit NDC (5-4-2 format)**	**Description**
57894-800-01	**57894-0800-01**	One single-dose vial containing 300 mg/1.62 mL (185 mg/mL) for intravenous injection
57894-801-01	**57894-0801-01**	One single-dose vial containing 1200 mg/6.5 mL (185 mg/mL) for intravenous injection

Coding for IMAAVY

The following codes may be relevant for seeking reimbursement for IMAAVY. For the most accurate coding and billing requirements, please confirm with your payer.

ICD-10-CM wAIHA Diagnosis Code[3]

ICD-10-CM Code for Consideration	
D59.11	Warm type (primary) (secondary) (symptomatic) autoimmune hemolytic anemia
	Warm type autoimmune hemolytic disease

This code is not intended to promote, encourage, or suggest use of a drug that is inconsistent with FDA-approved use. This list is not exhaustive, additional codes may apply, and listed codes may require a higher level of specificity when reporting for individual patients. Please consult your ICD-10-CM codebook for more information.

HCPCS Code[4]

IMAAVY has a permanent J-code. Please refer to the coding information below to support appropriate claims processing for IMAAVY. Always check specific payer requirements when submitting claims for IMAAVY.

J9256 | **Injection, nipocalimab-aahu, 3 mg[4]**

Please refer to sample claim forms beginning on page 6 for additional information.

FDA, U.S. Food & Drug Administration; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification.

Please see full Important Safety Information for IMAAVY on page 12.
Please read accompanying full Prescribing Information.

Coding for IMAAVY (cont.)

Current Procedural Terminology (CPT®) Codes for Drug Administration[5]

Payer policies for codes that describe drug administration services may vary; contact your payer for their code requirements.

CPT® Code	Descriptor
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

NOTE: An infusion of 15 minutes or less is an intravenous push.

Place of Service Codes[2]

Code	Place of Service
11	Office
19	Off campus - outpatient hospital
22	On campus - outpatient hospital

Revenue Codes[6]

Code	Descriptor
0260	IV (intravenous) therapy, general
0510	Clinic, general
0636	Pharmacy, drugs requiring detailed coding

NOTE: Many payers require revenue codes for hospital outpatient department claims.

HCPCS Modifiers[7,8]

Modifier	Descriptor
JW	Drug amount discarded/not administered to any patient
JZ	No discarded drug amounts
TB	Drug or biological acquired with 340B pricing program discount, reported for informational purposes

HCPCS, Healthcare Common Procedure Coding System.

Please see full Important Safety Information for IMAAVY on page 12.
Please read accompanying full Prescribing Information.

Sample Claims Forms for IMAAVY

Sample CMS-1500 Form

Total Dose: IMAAVY 2580-mg IV

Use to submit claims for IMAAVY administered in your office

1

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. D59.11 B. C. D.

E. F. 3 G. 4 H. 5

I. J. K. L.

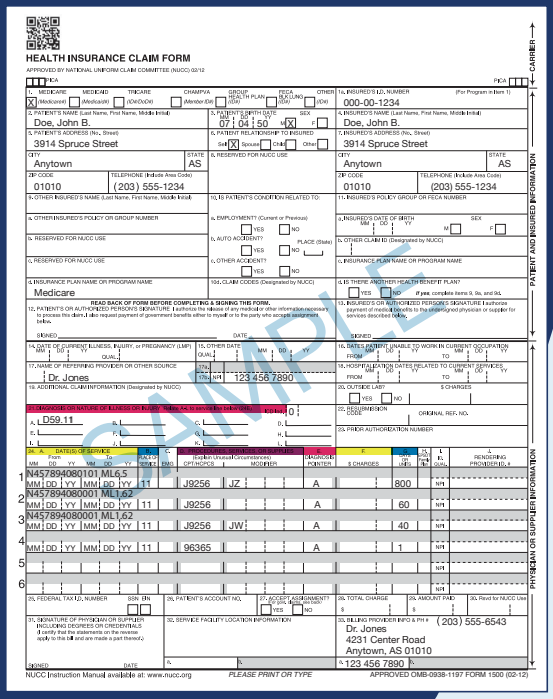
22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER 6 7

2

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N457894080101 ML6.5											
MM DD YY	MM DD YY	11		J9256	JZ	A		800		NPI	
2 N457894080001 ML1.62											
MM DD YY	MM DD YY	11		J9256		A		60		NPI	
3 N457894080001 ML1.62											
MM DD YY	MM DD YY	11		J9256	JW	A		40		NPI	
4											
MM DD YY	MM DD YY	11		96365		A		1		NPI	

PHYSICIAN OR SUPPLIER INFORMATION



Check with the individual payer, as specific claim requirements may vary.

For detailed guidance on completing CMS-1500 items, refer to Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf[2]

These documents are presented for informational purposes only and are not intended to provide reimbursement or legal advice, nor do they promise or guarantee coverage, levels of reimbursement, payment, or charge.

CMS, Centers for Medicare & Medicaid Services; IV, intravenous.

Please see full Important Safety Information for IMAAVY on page 12.

Please read accompanying full Prescribing Information.

Sample Claims Forms for IMAAVY (cont.)

Sample CMS-1500 Form (cont.)

1

ITEM 21

Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

2

ITEM 24A

If line item NDC information is required, it will be entered in the shaded portion of Item 24A.[2] Payer requirements for NDC entries may vary.

3

ITEM 24B

Identify the location where the service was rendered.

4

ITEM 24D

Indicate appropriate CPT® and HCPCS codes and modifiers as required by payer.

IMAAVY

- **J9256:** Injection, nipocalimab-aahu, 3 mg

Modifiers

- Required for Medicare Part B claims
- Ensure modifier(s) JZ, JW, or both are included for J9256 claims
  - Use the JZ modifier on line item entries when the entire vial is administered (no discarded drug)
  - For vials with waste, use the JW modifier on line item entries for discarded units. Do not add a modifier to the line item for administered units
- Check payer requirements when submitting non-Medicare claims

Infusion Services

- **CPT® 96365:** Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour; or
- **CPT® 96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

Note: An infusion of 15 minutes or less is an intravenous push.

5

ITEM 24E

Refer to the diagnosis for this service (see Item 21). Enter only one diagnosis pointer per line.

6

ITEM 24F

Indicate total charges.

7

ITEM 24G

- **J9256:** Enter the number of HCPCS units: 3 mg = 1 unit (300 mg = 100 units)*
- **CPT® 96365 or 96413:** Enter 1 unit for the first hour of infusion

*If more than 999 units are required, an additional line on the claim may be necessary.

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

Please see full Important Safety Information for IMAAVY on page 12.
Please read accompanying full Prescribing Information.

Sample Claims Forms for IMAAVY (cont.)

Sample CMS-1450 Form

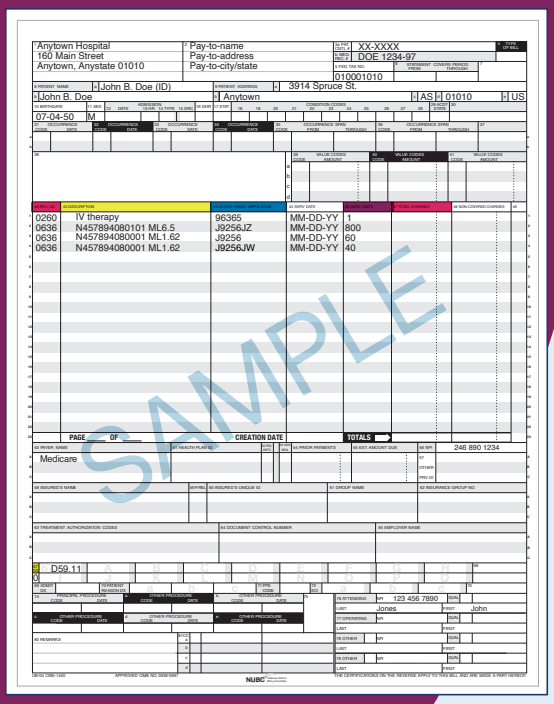
Total Dose: IMAAVY 2580-mg IV

Use to submit claims for IMAAVY administered in a hospital outpatient setting

	42 REV. CD	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0260	IV therapy	96365	MM-DD-YY	1			
2	0636	N457894080101 ML6.5	J9256JZ	MM-DD-YY	800			
3	0636	N457894080001 ML1.62	J9256	MM-DD-YY	60			
4	0636	N457894080001 ML1.62	J9256JW	MM-DD-YY	40			
5								

6

67 DX	D59.11	A
0		J
69 ADMIT DX		70 PATIENT REASON DX
74 PRINCIPAL PROCEDURE CODE	DATE	a.
c. OTHER PROCEDURE CODE	DATE	d.
80 REMARKS		



Check with the individual payer, as specific claim requirements may vary.

For detailed guidance on completing CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf[9]

CMS, Centers for Medicare & Medicaid Services; IV, intravenous.

Please see full Important Safety Information for IMAAVY on page 12.
Please read accompanying full Prescribing Information.

Sample Claims Forms for IMAAVY (cont.)

Sample CMS-1450 Form (cont.)

1

BOX 42

List revenue codes in ascending order.

2

BOX 43

Enter narrative description for corresponding revenue code (eg, IV therapy, drug). Alternatively, if line item NDC information is required, please enter it in the unshaded portions of Locator Box 43.[9] Payer requirements for NDC entries may vary.

3

BOX 44

Indicate appropriate CPT®, HCPCS codes, and modifiers as required by the payer.

IMAAVY

- **J9256:** Injection, nipocalimab-aahu, 3 mg

Modifiers

- Required for Medicare Part B claims
- Ensure modifier(s) JZ, JW, or both are included for J9256 claims
  - Use the JZ modifier on line item entries when the entire vial is administered (no discarded drug)
  - For vials with waste, use the JW modifier on line item entries for discarded units. Do not add a modifier to the line item for administered units
- For drugs acquired with 340B pricing program discount, the TB modifier is required
- Check payer requirements when submitting non-Medicare claims

Infusion Services

- **CPT® 96365:** Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour; or
- **CPT® 96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

Note: An infusion of 15 minutes or less is an intravenous push.

4

BOX 46

Enter the number of units:

- **CPT® 96365 or 96413**: Enter 1 unit for the first hour of infusion
- **J9256:** Enter the number of HCPCS units: 3 mg = 1 unit (300 mg = 100 units)*

5

BOX 47

Indicate total charges.

6

BOX 67

Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service, and enter the diagnoses in priority order.

*If more than 999 units are required, an additional line on the claim may be necessary.

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code.

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Please read accompanying full Prescribing Information.

Claim Filing Checklist

Once your patient receives IMAAVY, you'll need to submit a claim for reimbursement to their health insurance provider. It is important to be familiar with the payer's specific billing and coding requirements and ensure that your claim is complete and accurate. Use appropriate codes to report the patient's condition, the drugs the patient received, and the services you have provided.

The following code types are generally required when filing claims for IMAAVY:

- ☐ ICD-10-CM code/patient diagnosis
- ☐ Drugs administered
  - NDC (11-digit format may be required in addition to the HCPCS code)
  - HCPCS code, confirm billing units (reminder 3 mg = 1 unit or 300 mg = 100 units)
- ☐ Services provided
  - Drug administration: CPT® codes
  - Other: CPT® codes
- ☐ HCPCS/CPT® modifiers as required by payer
  - JZ (no discarded drug); JW (amount of drug discarded)
  - TB (drug acquired with 340B pricing discount program)

Prior to claim submission:

- ☐ Review the claim for completeness and coding alignment with payer requirements.
- ☐ Include any additional documentation the payer requires (eg, prior authorization number, drug invoice).
- ☐ File the claim as soon as possible and within the payer's filing time limits.
- ☐ Establish a tracking and reconciliation process to follow claims through payment.

For billing and coding or reimbursement questions, or to request support from a Field Reimbursement Manager (FRM), call **844-494-8463**, Monday-Friday, 8 AM to 8 PM ET.

Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a medical benefit and delivered to the administering provider. When a third party supplies the drug at no cost to the provider, the drug should NOT be billed to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered had the physician purchased it.

When reporting drug administration services with no drug charge, it is common to require the drug HCPCS code on the same claim. To accommodate claim-processing edits, it may also be necessary to include a charge of $0.01.[10] Payer policies may vary.

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

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Patient Access and Support

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.

Support for Healthcare Providers

Access & Affordability Support

Your Case Manager team can help verify insurance coverage, assess patient eligibility for cost support options and offer the IMAAVY withMe Access Program to eligible commercial patients when coverage is delayed more than 5 business days or denied.

Office Educational Support

Get customized patient fulfillment support from a dedicated team that includes a Case Manager and a Field Reimbursement Manager.

Support for Patients

Dedicated Nurse Navigator*

A dedicated Nurse Navigator is a registered nurse who is available to support your patients with disease education and disease management resources.

*Nurse Navigators do not provide medical advice.

For patients using commercial or private insurance

IMAAVY withMe Savings Program

Your eligible patients pay as little as $0 per infusion

Program consists of **Medicine Cost Support** for the cost of IMAAVY medicine and **Treatment Administration Cost Support** for certain IMAAVY infusion administration and related monitoring costs. Maximum program benefit per calendar year shall apply. Offer subject to change or end without notice.

See program requirements at IMAAVYwithMeSavings.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.

For assistance with patient support or billing and coding questions, please contact IMAAVY withMe at **844-4withMe (844-494-8463)** or visit JNJwithMe.com/hcp/IMAAVY

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

References: 1. IMAAVY [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26: Completing and Processing the Form CMS-1500 Data Set. Revised August 9, 2024. Accessed July 7, 2026. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **3.** Centers for Medicare & Medicaid Services. 2026 ICD-10-CM. June 5, 2026. Accessed July 7, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes#CodeFiles **4.** 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. Published October 21, 2025. Accessed July 7, 2026. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-3-2025-drugs-biologicals.pdf **5.** American Medical Association. Current Procedural Terminology: CPT® 2025: Professional Edition. Chicago, IL: American Medical Association; 2024. **6.** Noridian Healthcare Solutions. Revenue Codes. Last updated February 12, 2026. Accessed July 7, 2026. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **7.** Centers for Medicare & Medicaid Services. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed July 7, 2026. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **8.** Centers for Medicare & Medicaid Services. Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier. November 2024. Accessed July 7, 2026. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf **9.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25: Completing and Processing the Form CMS-1450 Data Set. Revised December 20, 2023. Accessed July 7, 2026. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf **10.** Centers for Medicare & Medicaid Services. Billing and Coding: Patients Supplied Donated or Free-of-Charge Drug. Revised November 22, 2023. Accessed July 7, 2026. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55045

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imaavy® (nipocalimab-aahu)

Important Safety Information

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.

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.

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.

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.

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.

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.

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.

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

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