imaavy™
(nipocalimab-aahu)

IMAAVY™ Billing & Coding Guide

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 page 12.

Johnson&Johnson

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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™ (nipocalimab-aahu).

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]

IMAAVY™ dosing for adult and pediatric patients 12 years and older with gMG:

Initial Dose

30 mg/kg administered intravenously over **at least 30 minutes**

Maintenance Doses every 2 weeks thereafter

15 mg/kg administered intravenously over **at least 15 minutes**

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

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

Missed Dose: 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.

- Prior to administration, IMAAVY™ single-dose vials require dilution in 0.9% sodium chloride injection, USP, to a final volume of 250 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™.

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**
57894-801-01	**57894-0801-01**	One single-dose vial containing 1,200 mg/6.5 mL (185 mg/mL) for intravenous injection

The 300-mg vial is anticipated to be commercially available in the first quarter of 2026.

gMG, generalized myasthenia gravis.

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

Coding for IMAAVY™

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

ICD-10-CM Diagnosis Codes[3]

ICD-10-CM Codes for Consideration	
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

These codes are 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.

Healthcare Common Procedure Coding System (HCPCS) Codes[4]

As a newly approved drug, IMAAVY™ does not yet have a unique HCPCS code. Miscellaneous/unclassified codes allow immediate billing as soon as the FDA allows it to be marketed, while awaiting assignment of a permanent code. Required reporting of miscellaneous drug codes can vary by site of care, payer, and timing after FDA approval.

Transition to Permanent HCPCS Code

Site of Care	Payer	Coding Following FDA Approval Up to Assignment of a Permanent HCPCS Code	Permanent HCPCS Code
Physician Office	All payers	**J3490** – Unclassified drugs* **J3590** – Unclassified biologics*	

Site of Care	Payer	Coding Immediately Following FDA Approval	Anticipated October 1, 2025
Hospital Outpatient Department	Medicare	**C9399** – Unclassified drugs or biologics	Temporary, drug-specific code
	Non-Medicare†	**J3490** – Unclassified drugs* **J3590** – Unclassified biologics*	

Anticipated January 1, 2026

*As required by payer.
†Includes Medicare Advantage.

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

Medicare Payment Considerations for New Drugs[5,6]

- The absence or presence of a HCPCS code, NDC, or payment allowance limit in the files does not indicate whether Medicare covers a particular product.
- Even if a product does not appear on a quarter's national price file, it may still be paid by the local contractor that processes the Part B claim, provided that the claim is reasonable and necessary and meets all necessary requirements for payment. In such a case, the local contractor will also determine the payment amount.
- Each Medicare Administrative Contractor (MAC) will make a local determination of wholesale acquisition cost (WAC) or invoice-based payment.

ICD-10-CM, International Classification of Disease, 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.

Coding for IMAAVY™ (cont.)

Current Procedural Terminology (CPT®) Codes for Drug Administration[7]

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[8]

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

NOTE: Many payers require this for hospital outpatient department claims.

HCPCS Modifiers[9,10]

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.

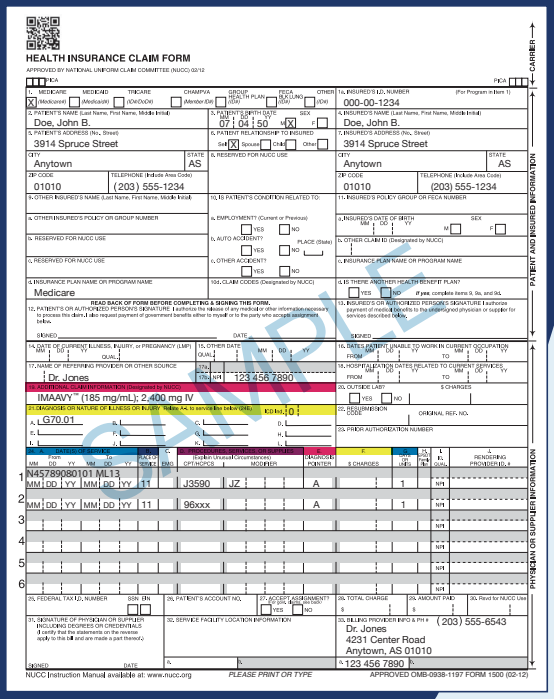
Sample Claims Forms for IMAAVY™

Sample CMS-1500 Form

Initial Dose: IMAAVY™ 2,400-mg IV

Use to submit claims for IMAAVY™ administered in your office

1	19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) IMAAVY™ (185 mg/mL); 2,400 mg IV															20. OUTSIDE LAB? ☐ YES ☐ NO			$ CHARGES				
2	21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0															22. RESUBMISSION CODE			ORIGINAL REF. NO.				
	A. G70.01		B.		C.		D.									23. PRIOR AUTHORIZATION NUMBER							
	E.		F. 4		G. 5		H. 6									7		8					
3	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	N45789080101 ML13 MM DD YY	MM DD YY	11		J3590	JZ	A		1		NPI												
2	MM DD YY	MM DD YY	11		96xxx		A		1		NPI												


HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE ☒ | MEDICAID | TRICARE | CHAMPVA | GROUP HEALTH PLAN | FECA BLK LUNG | OTHER

1a. INSURED'S I.D. NUMBER: 000-00-1234

2. PATIENT'S NAME: Doe, John B.

3. PATIENT'S BIRTH DATE: 07 04 50 SEX: M ☒ F

4. INSURED'S NAME: Doe, John B.

5. PATIENT'S ADDRESS: 3914 Spruce Street

6. PATIENT RELATIONSHIP TO INSURED: Self ☒ Spouse Child Other

7. INSURED'S ADDRESS: 3914 Spruce Street

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

CITY: Anytown STATE: AS

ZIP CODE: 01010 TELEPHONE: (203) 555-1234

9. OTHER INSURED'S NAME

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

ZIP CODE: 01010 TELEPHONE: (203) 555-1234

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED

DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE MM DD YY QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones

17a. QUAL. 1ORNPI: 123 456 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): IMAAVY™ (185 mg/mL); 2,400 mg IV

20. OUTSIDE LAB? YES NO $ CHARGES

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

A. G70.01 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

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 N45789080101 ML13 MM DD YY	MM DD YY	11		J3590	JZ	A		1		NPI	
2 MM DD YY	MM DD YY	11		96xxx		A		1		NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH # (203) 555-6543

Dr. Jones
4231 Center Road
Anytown, AS 01010

a. 123 456 7890 b.

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

CARRIER

SAMPLE

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

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 19

NOC codes are not drug specific; enter additional detail here. Payer requirements, including need for additional documentation (eg, drug wastage, NDC, drug invoice), may vary. Please verify with your payer.

2

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.

3

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.

4

ITEM 24B

Identify the location where the service was rendered.

5

ITEM 24D

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

IMAAVY™
- **J3590:** Unclassified biologics; or
- **J3490:** Unclassified drugs

Modifiers
Required by Medicare
- **JZ:** To be reported for drugs from single-use containers billed with an NOC code in the physician office.
- **Non-Medicare Payers:** As required by payer.

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.

6

ITEM 24E

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

7

ITEM 24F

Indicate total charges.

8

ITEM 24G

Enter the number of units:
- **J3590:** Unclassified drug codes are reported as a unit of "1," regardless of dose.
- **CPT® 96365 or 96413:** Enter 1 unit for the first hour of infusion.

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; NOC, not otherwise classified.

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

Initial Dose: IMAAVY™ 2,400-mg IV

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

1	2	3		4	5
42 REV. CD	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	d	46 SERV. UNITS	47 TOTAL CHARGES
0260	IV therapy	96xxx	MM-DD-YY	1	
0636	N45789080101ML13	C9399	MM-DD-YY	1	

6

67 DX: G70.01

0

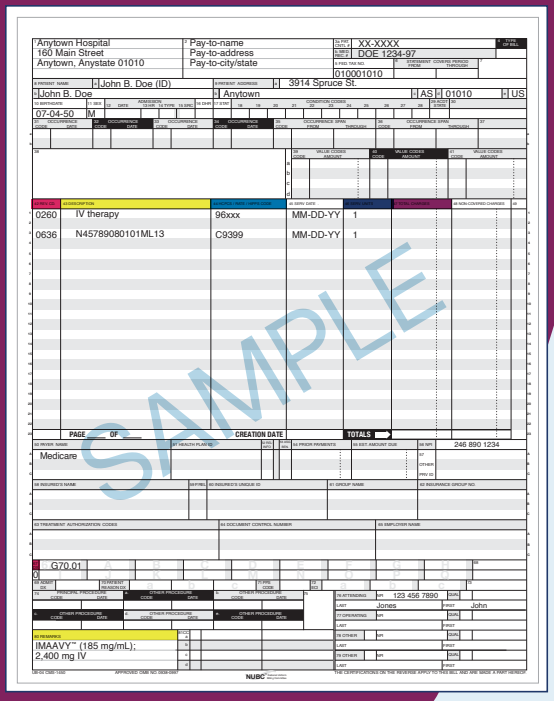
69 ADMIT DX | 70 PATIENT REASON DX

74 PRINCIPAL PROCEDURE CODE DATE a.

c. OTHER PROCEDURE CODE DATE d.

7

80 REMARKS: IMAAVY™ (185 mg/mL); 2,400 mg IV



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[11]

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.[11] Payer requirements for NDC entries may vary.

3

BOX 44

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

IMAAVY™
- **C9399:** Unclassified drugs or biologics

Modifiers
Medicare:
- The JZ modifier does not apply to C9399.
- For drugs acquired with 340B pricing program discount, the TB modifier is required.

Non-Medicare:
- As required by payer

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.
- **C9399:** Unclassified drug codes are reported as a unit of "1," regardless of dose.

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.

7

BOX 80

NOC codes are not drug specific; enter additional detail here. Payer requirements, including need for additional documentation (eg, drug wastage, NDC, drug invoice), may vary. Please verify with your payer.

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; NOC, not otherwise classified.

Please see full Important Safety Information for IMAAVY™ on page 12.
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 (for NOC codes, include payer-required details/supporting documentation)
- ☐ 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.[12] 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; NOC, not otherwise classified.

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

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.

Infusion Services

IMAAVY withMe Infusion Services utilizes a contracted network of Infusion Service Providers (ISPs)† to coordinate continuity of care and support the overall patient experience by leveraging existing infrastructure and clinical expertise.

*Nurse Navigators do not provide medical advice. Patient Authorization is required for enrollment in Nurse Navigator support.

†The contracted ISPs are not the only ISPs available, and Johnson & Johnson does not endorse the use of any infusion service providers in particular. The information provided represents no statement, promise, or guarantee of Johnson & Johnson concerning levels of reimbursement, payment, or charge. Please consult specific payer organizations with regard to local or actual coverage, reimbursement policies, and determination processes.

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**

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 December 14, 2023. Accessed February 5, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **3.** Centers for Medicare & Medicaid Services. 2025 ICD-10-CM. February 25, 2025. Accessed March 19, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes#CodeFiles **4.** Centers for Medicare & Medicaid Services. April 2025 Alpha-Numeric HCPCS Files. Updated March 26, 2025. Accessed March 31, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **5.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. Revised February 15, 2024. Accessed February 25, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf **6.** Centers for Medicare & Medicaid Services. ASP Pricing Files. Updated March 27, 2025. Accessed April 1, 2025. https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files **7.** American Medical Association. Current Procedural Terminology: CPT® 2025: Professional Edition. Chicago, IL: American Medical Association; 2024. **8.** Noridian Healthcare Solutions. Revenue Codes. Last updated March 18, 2024. Accessed February 5, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **9.** Centers for Medicare & Medicaid Services. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed February 5, 2025. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf **10.** Centers for Medicare & Medicaid Services. Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier. December 14, 2023. Accessed March 19, 2025. https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf **11.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25: Completing and Processing the Form CMS-1450 Data Set. Revised February 5, 2025. Accessed March 19, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf **12.** Centers for Medicare & Medicaid Services. Billing and Coding: Patients Supplied Donated or Free-of-Charge Drug. Revised November 22, 2023. Accessed March 19, 2025. https://www.cms. gov/medicare-coverage-database/view/article.aspx?articleid=55045

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; NOC, not otherwise classified.

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

Johnson&Johnson

imaavy™ (nipocalimab-aahu)

Important Safety Information

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.

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 see 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.

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imaavy™ (nipocalimab-aahu)