



Announcing a Unique **J9038**
J-Code for Niktimvo

Billing & Coding Guide

- ▶ Coverage, Coding, & Payment for Niktimvo
- ▶ Example Claims Forms – CMS-1500 & CMS-1450
- ▶ Best Practices for Timely Reimbursement
- ▶ IncyteCARES for Niktimvo – Patient Support Program Overview

This Billing and Coding Guide is intended to provide an overview of coding and coverage information for Niktimvo. Please use this guide to support the reimbursement process and as a source of information on IncyteCARES for Niktimvo.

While this guide provides information on navigating the reimbursement process, please note all enclosed coding information is for reference purposes only 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 specific payer guidance and requirements.

Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

**For questions regarding reimbursement and access for Niktimvo, please call
IncyteCARES at 1-855-452-5234, M–F, 8 AM to 8 PM ET**

Coverage & Payment for Niktimvo™ (axatilimab-csfr)

Coverage and payment methodology for Niktimvo will vary by payer type.

For Medicare patients, Niktimvo will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.

For patients enrolled in a commercial health plan, Medicare Advantage, or Medicaid, coverage of Niktimvo will vary by payer. Some payers may also apply utilization restrictions for Niktimvo. However, providers should be prepared to possibly go through the prior authorization process when seeking coverage.

Payment Methodology



Medicare

Until Average Sales Price (ASP) is established, Medicare reimbursement for an approved product is typically Wholesale Acquisition Cost (WAC) + 3% or 95% of Average Wholesale Price (AWP).*



Commercial Payers & Medicaid

Drug reimbursement will vary by payer but is generally the contracted reimbursement rate between the payer and provider.

Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

*If Medicare sequestration is in effect, a statutory reduction to the payment is applied. Please visit CMS.gov for more information.

Indication

Niktimvo is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Niktimvo can cause infusion-related reactions. Infusion-related reactions, including hypersensitivity reactions, occurred in 18% of patients who received Niktimvo in the clinical trial (AGAVE-201), with Grade 3 or 4 reactions in 1.3%.

Premedicate with an antihistamine and an antipyretic for patients who have previously experienced an infusion-related reaction to Niktimvo. Monitor patients for signs and symptoms of infusion-related reactions, including fever, chills, rash, flushing, dyspnea, and hypertension. Interrupt or slow the rate of infusion or permanently discontinue Niktimvo based on severity of the reaction.

Please see additional Important Safety Information throughout.
Please see [Full Prescribing Information](#).

Coding for Niktimvo™ (axatilimab-csfr)

Please refer to the coding information below to support appropriate claims processing for Niktimvo. Payer requirements for coding may vary. For the most accurate list of codes and billing requirements, please confirm with the individual payer.

National Drug Codes (NDCs)

	10-Digit	11-Digit
9 mg/0.18 mL Vial	50881-034-12	50881-0034-12
22 mg/0.44 mL Vial	50881-023-11	50881-0023-11

HCPCS Coding

J9038	Injection, axatilimab-csfr, 0.1 mg
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The permanent J-code for Niktimvo applies from April 1, 2025. For earlier dates of service, verify appropriate miscellaneous codes with individual payers.

HCPCS Modifiers

JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

ICD-10-CM Diagnosis Codes

D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.09	Other complications of bone marrow transplant

Revenue Codes

Administration	Drug
0335 Chemotherapy Administration - IV	0636 Drugs requiring detailed coding

Drug Administration / CPT® Code

96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial drug
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CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IV, intravenous.

Please see Important Safety Information throughout.
Please see [Full Prescribing Information](#).

Effective April 1, 2025, Niktimvo Has a Unique J-Code

J9038

**Injection,
axatilimab-csfr,
0.1 mg**

Billing Unit Conversion

J9038 Billing Unit = 0.1 mg

Single-Use Vial Sizes	9 mg	11 mg
Billing Units Per Vial	90 Units	220 Units

The total number of mg administered will vary based on patient weight.

When billing for Niktimvo, be sure to bill as milligram (mg) dosage for the number of units (e.g., 12 mg = 120 units, 17 mg = 170 units), not vials or mL.

The permanent J-code for Niktimvo is effective for dates of service on or after April 1, 2025. For dates of service prior to April 1, 2025, consult with the individual payer's policies to ensure you are using the appropriate miscellaneous codes for payer-specific reimbursement needs.



Payer requirements regarding detailed claim form information may vary. It is important to check with individual payers on their specific requirements and ensure accurate documentation of services and units of measure.

For questions regarding billing, coding, or reimbursement for Niktimvo, call IncyteCARES to be connected with a Field Access Manager

1-855-452-5234
M–F, 8 AM to 8 PM ET

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (Continued)

Embryo-Fetal Toxicity

Based on its mechanism of action, Niktimvo may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 44% of patients who received Niktimvo (N=79). Serious adverse reactions in > 2 patients included infection (pathogen unspecified) (14%), viral infection (14%), and respiratory failure (5.1%). Permanent discontinuation of Niktimvo due to an adverse reaction occurred in 10% of patients and dose reduction due to adverse reaction occurred in 8% of patients. Dose interruptions due to an adverse reaction occurred in 44% of patients. The adverse reactions leading to dose interruption in > 2 patients were viral infection, infection (pathogen unspecified), bacterial infection, musculoskeletal pain, and pyrexia.

Please see additional Important Safety Information throughout.
Please see [Full Prescribing Information](#).

 **Niktimvo**[™]
(axatilimab-csfr)
50 mg/mL for injection, for intravenous use

Using the JW & JZ Modifiers for Accurate Claims

It is important to use the correct modifier to reflect any wastage.

The JW and JZ modifiers are HCPCS Level II modifiers used for claims that bill for single-dose container drugs. Improper use or omission of the JW and JZ modifiers may result in returned claims, requiring resubmission.

While Niktimvo™ (axatilimab-csfr) is distributed in a single-dose vial, its dosage is based on the patient's weight, which may result in leftover medication that must be discarded, but is eligible for payment under the discarded drug policy. In these cases, the JW modifier is used to report wastage. When using the JW modifier to bill for discarded drugs, the amount administered should be rounded up to the next billing unit. In the event there is no wastage, the JZ modifier is used to indicate that no amount of drug was discarded or eligible for payment.

JW Modifier: Reporting Wastage

Two claim lines will be used:

- 1 J9038 No Modifier Units Administered
- 2 J9038 JW Modifier Units Wasted

JZ Modifier: Documenting No Wastage

Use a single claim line:

- 1 J9038 JZ Modifier Units Administered

Example 1: 40 kg patient

Administered 0.3 mg/kg of Niktimvo, equal to 12 mg of Niktimvo, drawn from two 9 mg/0.18 mL single-use vials
In this example, the JW modifier is used to report 6 mg (.12 mL) of wastage on the CMS-1500 Claim Form.

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)				E. DIAGNOSIS POINT	F. \$ CHARGES		G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
MM	DD	YY	MM	DD	YY			CPT/HCPCS		MODIFIER								
N450881003412			ML0.24															
MM	DD	YY	MM	DD	YY	11		J9038						\$	120		NPI	
N450881003412			ML0.12															
MM	DD	YY	MM	DD	YY	11		J9038		JW				\$	60		NPI	

Example 2: 70 kg patient

Administered 0.3 mg/kg of Niktimvo, equal to 21 mg of Niktimvo, drawn from one 22 mg/0.44 mL single-use vial
In this example, the JW modifier is used to report 1 mg (.02 mL) of wastage on the CMS-1450 Claim Form.

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 0636	N450881002311 ML0.42	J9038	MM-DD-YY	210	\$		1
2 0636	N450881002311 ML0.02	J9038 - JW	MM-DD-YY	10	\$		2
3 0636	N450881002311 ML0.02	J9038 - JW	MM-DD-YY	10	\$		3

Example 3: 60 kg patient

Administered 0.3 mg/kg of Niktimvo, equal to 18 mg of Niktimvo, drawn from two 9 mg/0.18 mL single-use vials
In this example, the JZ modifier is reported to denote no drug was discarded on the CMS-1450 Claim Form.

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 0636	N450881003412 ML0.18	J9038 - JZ	MM-DD-YY	180	\$		1

Inclusion of the JZ or JW modifier is required for timely reimbursement and approval of claims.

Questions? Contact your Field Access Manager or call IncyteCARES for Niktimvo at 1-855-452-5234, M-F, 8 AM to 8 PM ET

The permanent J-code for Niktimvo applies from April 1, 2025. For earlier dates, verify coding with payers.
HCPCS, Healthcare Common Procedure Coding System.

Please see Important Safety Information throughout.
Please see Full Prescribing Information.

Niktimvo™
(axatilimab-csfr)
50 mg/mL for injection, for intravenous use

This example form is provided for guidance and reference only.

The following example form is completed for a 70 kg patient, administered 0.3 mg/kg of Niktimvo (equal to 21 mg), drawn from one 22 mg/0.44 mL single-use vial, in the physician office setting.

Some payers may require additional information for proper processing. This may include*: *Drug name, strength, route of administration, dosage administered, amount wasted (if applicable), and NDC*

Enter the ICD-10-CM diagnosis code

Enter the date of service and appropriate place of service code. Each unique NDC used should be listed as its own line item. If NDC reporting is required, include the following in the shaded portion of Box 24A*: *N4+11-Digit NDC+ML+Unit Quantity (administered or discarded)*

- ▶ Drug - J9038 (Injection, axatilimab-csf_r, 0.1 mg)[†]
- ▶ Modifier - JW (Discarded product should be reported on a separate line with the JW modifier. If no wastage, include the JZ modifier inline with the HCPCS code)
- ▶ Administration - 96413

Refer to the diagnosis (Box 21), relating to the drug or procedure listed in Box 24D

Enter number of units for each line item. If a separate line was created for wastage, clearly indicate number of units discarded

- ▶ J9038 Billing Unit = 0.1 mg
- ▶ Single Dose Vial = 9 mg or 22 mg
- ▶ 9 mg Vial = 90 Units
- ▶ 22 mg Vial = 220 Units

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Niktimvo™ (axatilimab-csfr) Example CMS-1450 Claim Form

Hospital Outpatient Setting

This example form is provided for guidance and reference only.

Niktimvo and the associated services provided in a hospital outpatient setting are billed on the CMS-1450 Claim Form (or UB-40). It is always the provider's responsibility to determine the appropriate healthcare setting, and to submit true and correct claims for the products and services rendered. **Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.**

The following example form is completed for a 70 kg patient administered 0.3 mg/kg of Niktimvo (equal to 21 mg), drawn from one 22 mg/0.44 mL single-use vial, in the hospital outpatient setting.

Box 42

List the appropriate revenue code for each service provided. Drugs billed with HCPCS codes usually require revenue code 0636 (drugs requiring detailed coding)

Box 43

Enter a description for each revenue code. Each unique NDC used should be listed as its own line item

If NDC reporting is required, include the following*: *N4+11-Digit NDC+ML+Unit Quantity (administered or discarded)*

Box 44

Enter the appropriate HCPCS, modifier, and CPT® codes. For example:

- ▶ Drug - J9038 (Injection, axatilimab-csfr, 0.1 mg)*
- ▶ Modifier - JW (Discarded product should be reported on a separate line with the JW modifier. If no wastage, include the JZ modifier inline with the HCPCS code)
- ▶ Administration - 96413

Box 45

Enter the date of service

Box 46

Enter number of units for each line item. If a separate line was created for wastage, clearly indicate number of units discarded

- ▶ J9038 Billing Unit = 0.1 mg
- ▶ 1 Single Dose Vial = 9 mg or 22 mg
- ▶ 9 mg Vial = 90 Units
- ▶ 22 mg Vial = 220 Units

Box 67

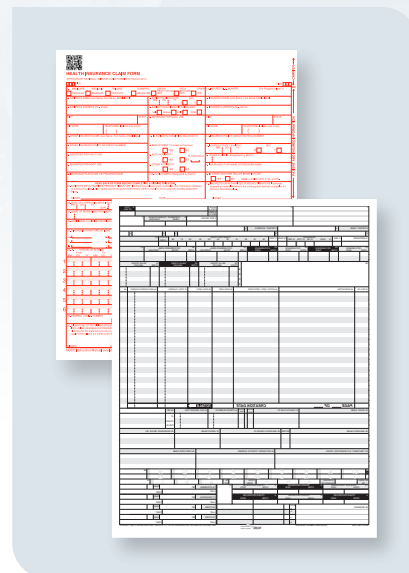
Enter the ICD-10-CM diagnosis code

1		2		3a PAT CONTL # b MED REC #		4 TYPE OF BILL	
5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM		7 THROUGH			
8 PATIENT NAME				9 PATIENT ADDRESS			
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION	
14 TYPE		15 SRC		16 DHR		17 STAT	
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26		27		28		29	
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Best Practices for Timely Claims Reimbursement

For an efficient claims and reimbursement process, employ the following strategies:

- ▶ **Verify accuracy** of patient information
- ▶ **Use the Niktimvo specific J-code:** J9038 (Injection, axatilimab-csfr, 0.1 mg) when completing the 1450 or 1500 Claims Form for claims on or after April 1, 2025
- ▶ **Ensure accurate coding** - refer to the Niktimvo Billing & Coding Guide for appropriate codes and modifiers (e.g., CPT®, HCPCS, ICD-10-CM)
 - > Reference the included Example Claims Forms for guidance on accurately recording appropriate codes and supplemental information
- ▶ **Include correct number** of units administered and discarded (when applicable)
 - > 9 mg single-use vial is equal to 90 billing units
 - > 22 mg single-use vial is equal to 220 units
- ▶ **Include correct modifier** to report product wastage / no product discarded
 - > JW modifier must be reported on a separate line in the event of wastage
 - > If no product was discarded, record the JZ Modifier on the same line as the HCPCS code
- ▶ **Ensure accuracy** of information needed to process the claim
 - > Correct NDC Format – use 10- or 11-digit format based on payer requirements
 - > Prior Authorization Number, if applicable
- ▶ **Check your payer agreements** to ensure you understand any specific reimbursement needs for Niktimvo, and follow the payer's recommendations for providing additional information (e.g., medical records)
- ▶ **Make sure** electronic claims are successfully submitted
- ▶ **Stay up to date** with payer coverage policies



To request assistance with billing, coding, or reimbursement questions, contact IncyteCARES to be connected with a Field Access Manager

Call 1-855-452-5234, M–F, 8 AM to 8 PM ET

The information herein is provided for educational purposes only. Insurance coverage and reimbursement are not guaranteed. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

*The permanent J-code for Niktimvo applies from April 1, 2025. For earlier dates, verify coding with payers.

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 Important Safety Information throughout.
Please see [Full Prescribing Information](#).

 **Niktimvo™**
(axatilimab-csfr)
50 mg/mL for injection, for intravenous use

IncyteCARES for Niktimvo™ (axatilimab-csfr) Patient Support Program Overview

When You Enroll a Patient, an IncyteCARES for Niktimvo Representative Will:

- ▶ Call your patient to welcome them and explain their insurance coverage for Niktimvo
- ▶ Assess your patient's eligibility for savings or financial assistance programs,* and help them enroll
- ▶ Explain the additional support and resources available to them during treatment

*Terms and conditions apply. Program terms may change at any time.



**IncyteCARES for Niktimvo
Supports Your Eligible Patients
During Treatment.**

Our mission is to help patients start and stay on therapy by assisting with access and as-needed support.



For Eligible Patients With Commercial Health Insurance IncyteCARES for Niktimvo Savings Program

Eligible Patients Can Receive Niktimvo for As Little As \$15, Subject to Certain Limits†

To qualify, patients must:

- ▶ Have commercial healthcare coverage. Patients insured under federal or state government healthcare programs—including Medicare Part B, Medicare Advantage, Medicaid, TRICARE, or any state medical or pharmaceutical assistance program—are not eligible. Patients without healthcare coverage are also not eligible
- ▶ Be a resident of the United States or Puerto Rico
- ▶ Have a valid prescription for Niktimvo for an FDA-approved use

†Uninsured, cash-paying, or Alternate Funding Program (AFP) patients are not eligible. Not valid for patients insured through Medicare Part B, Medicare Advantage, Medicaid, TRICARE, or any state medical or pharmaceutical assistance program. Patient enrollment in a copay adjustment program, such as a maximizer or accumulator program, may impact the value of this offer. Annual benefit maximum applies, as may other restrictions. Program benefit applies to medication cost only and does not cover any costs to administer the medication. Valid prescription for Niktimvo™ (axatilimab-csfr) for an FDA-approved indication or compendia-recognized use is required. Please see the full [Patient Terms and Conditions](#) or call IncyteCARES for Niktimvo at 1-855-452-5234. Update effective as of September 1, 2024.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (Continued)

The most common ($\geq 15\%$) adverse reactions, including laboratory abnormalities, were increased aspartate aminotransferase (AST), infection (pathogen unspecified), increased alanine aminotransferase (ALT), decreased phosphate, decreased hemoglobin, viral infection, increased gamma glutamyl transferase (GGT), musculoskeletal pain, increased lipase, fatigue, increased amylase, increased calcium, increased creatine phosphokinase (CPK), increased alkaline phosphatase (ALP), nausea, headache, diarrhea, cough, bacterial infection, pyrexia, and dyspnea.

Please see Important Safety Information throughout.
Please see [Full Prescribing Information](#).

 **Niktimvo™**
(axatilimab-csfr)
50 mg/mL for injection, for intravenous use

IncyteCARES for Niktimvo™ (axatilimab-csfr) Patient Support Program Overview

Enroll Your Eligible Patient in IncyteCARES for Niktimvo



Completing the enrollment form takes about 15 minutes.
Simply download and complete the form, then fax it to **1-866-870-6241**.

Visit HCP.IncyteCARES.com/Niktimvo for more information

Other Financial Assistance and Support Options

When you enroll your patient in IncyteCARES for Niktimvo, we will also review their eligibility for the following programs:



*For Eligible Patients Who Are Uninsured
or Underinsured for Niktimvo*

**IncyteCARES for Niktimvo
Patient Assistance Program**



For All Patients

**Information About Nonprofit or
Other Support Organizations**

The IncyteCARES Team Is Available by Phone Every Weekday



Call 1-855-452-5234, M–F, 8 AM to 8 PM ET

Visit HCP.IncyteCARES.com/Niktimvo to learn more

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (Continued)

Clinically relevant adverse reactions in < 10% of patients who received Niktimvo included:

- *Eye disorders:* periorbital edema
- *Skin and subcutaneous skin disorders:* pruritus
- *Vascular disorders:* hypertension

Immunogenicity: Anti-Drug Antibody–Associated Adverse Reactions

Across treatment arms in patients with cGVHD who received Niktimvo in clinical trials, among the patients who developed anti-drug antibodies (ADAs), hypersensitivity reactions occurred in 26% (13/50) of patients with neutralizing antibodies (NAb) and in 4% (2/45) of those without NAb.

**Please see additional Important Safety Information throughout.
Please see [Full Prescribing Information](#).**

 **Niktimvo™**
(axatilimab-csfr)
50 mg/mL for injection, for intravenous use

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 30 days after the last dose of Niktimvo.

Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating Niktimvo.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose of Niktimvo.

DOSAGE AND ADMINISTRATION

Dosage Modifications for Adverse Reactions

Monitor aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase prior to the start of Niktimvo therapy, every 2 weeks for the first month, and every 1 to 2 months thereafter until abnormalities are resolved. See Table 1 in the Prescribing Information for more recommendations.

Please see [Full Prescribing Information](#) for Niktimvo.



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