



# Billing & Coding Guide

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**This Billing and Coding Guide is intended to provide an overview of Niktimvo coding and coverage information. 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 Niktimvo reimbursement and access, 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

Medicare reimbursement for a newly approved product is typically Wholesale Acquisition Cost (WAC) + 3% or 95% of Average Wholesale Price (AWP) until Average Sales Price (ASP) is established\*.



#### 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](#).

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

## 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

J9999	Not otherwise classified, antineoplastic drugs
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals – <i>Hospital Outpatient Setting</i>

### 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 Code

D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified

### Revenue Codes

Administration	Drug
<b>0335</b> Chemotherapy Administration - IV	<b>0636</b> Drugs requiring detailed coding

### Drug Administration / CPT® Codes

<b>96413</b>	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**.

## Using Miscellaneous Codes

Permanent J-codes are typically not assigned immediately upon FDA approval of a new product. Prior to Niktimvo™ (axatilimab-csfr) being assigned a permanent J-code, use the following information to help navigate the reimbursement process.

### What is a miscellaneous or unclassified code?

A miscellaneous code is used when there is no permanent code to describe a medication or service being billed. A miscellaneous code is also used when a new, permanent J-code under the HCPCS Level II system has not yet been assigned.

### Will I receive reimbursement if I bill using a miscellaneous code?

Miscellaneous J-codes (or C-codes in the hospital outpatient setting) are typically reimbursed if aligned with payer policies. Understanding a payer's specific requirements is important when submitting a claim for reimbursement.

### Which unclassified or miscellaneous code should I use?

Until a permanent J-code is assigned for Niktimvo, the appropriate HCPCS codes to use depend on payer preference and setting of care, and may include:

- ▶ **J3490** (unclassified drugs)
- ▶ **J9999** (not otherwise classified, antineoplastic drugs)
- ▶ **J3590** (unclassified biologics)
- ▶ **C9399** (unclassified drugs or biologicals) - *Hospital Outpatient Setting*

A permanent J-code for Niktimvo will be effective on April 1, 2025.

Always consult a payer's specific policies or contact the payer to ensure you are using the appropriate miscellaneous codes for payer-specific reimbursement needs.

## 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](#).

# 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 and eligible for payment.

When using a miscellaneous J- or C-code, include a line for each NDC / vial used, and include detailed information on amount administered and amount wasted (if applicable) in Box 19 (CMS-1500) or Box 80 (CMS-1450) for proper processing. For more information please see pages 6 and 7.

## 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.	C.	D. PROCEDURES, SERVICES, OR SUPPLIES				E.	F.	G.	H.	I.	J.
	From	To				PLACE OF	EMG	(Explain Unusual Circumstances)				DIAGNOSIS	\$ CHARGES	DAYS	EPSDT	ID.	RENDERING	
	MM	DD	YY	MM	DD	YY		CPT/HCPCS	MODIFIER				POINTER		OR	Plan	QUAL.	PROVIDER ID. #
N450881003412	ML0.18							J9999	JZ						1		NPI	
N450881003412	ML0.06							J9999						1		NPI		
N450881003412	ML0.12							J9999	JW					1		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	Niktimvo N450881002311 ML0.42	C9399	MM-DD-YY	1	\$\$		1
2							2
3 0636	Niktimvo N450881002311 ML0.02	C9399 - JW	MM-DD-YY	1	\$\$		3

**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**

HCPCS, Healthcare Common Procedure Coding System.

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

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

# Niktimvo™ (axatilimab-csfr) Example CMS-1500 Claim Form Physician Office Setting

This example form is provided for guidance and reference only.

Niktimvo and the associated services provided in a physician office setting are billed on the CMS-1500 Claim Form. 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 physician office setting.

## Box 19

When using a miscellaneous code, include detailed information for proper processing\*: *Drug name, strength, route of administration, dosage administered, amount wasted (if applicable), and NDC*

## Box 21

Enter the appropriate ICD-10-CM diagnosis code

## Box 24 A-B

Enter the date of service and the appropriate place of service code. When using a miscellaneous J-code, include the following in the shaded portion of Item 24A for each NDC\*: *N4+11-Digit NDC+ML+Unit Quantity (administered or discarded)*

## Box 24 D

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

- ▶ Drug - J9999 (Not otherwise classified, antineoplastic drugs)
- ▶ Modifier - JW (Discarded product should be reported on a separate line with the JW modifier. If no wastage occurs, include the JZ modifier inline with the HCPCS code)
- ▶ Administration - 96413

## Box 24 E

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

## Box 24 G

Enter the number of units for each line item. With miscellaneous codes, "1" is typically used, as these codes do not have a specific unit value, but payer requirements may vary

HEALTH INSURANCE CLAIM FORM													
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12													
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA (LUNG) <input type="checkbox"/> OTHER <input type="checkbox"/>										1a. INSURED'S I.D. NUMBER (For Program in Item 1)			
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)										3. PATIENT'S BIRTH DATE (MM DD YY)		SEX (M <input type="checkbox"/> F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No., Street)						6. PATIENT RELATIONSHIP TO INSURED (Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>						7. INSURED'S ADDRESS (No., Street)	
CITY				STATE		CITY				STATE			
ZIP CODE				TELEPHONE (Include Area Code)				ZIP CODE				TELEPHONE (Include Area Code)	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)										10. IS PATIENT'S CONDITION RELATED TO:		11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. OTHER INSURED'S POLICY OR GROUP NUMBER				a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>				a. INSURED'S DATE OF BIRTH (MM DD YY)				SEX (M <input type="checkbox"/> F <input type="checkbox"/>	
b. RESERVED FOR NUCC USE				b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>				b. OTHER CLAIM ID (Designated by NUCC)					
c. RESERVED FOR NUCC USE				c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>				c. INSURANCE PLAN NAME OR PROGRAM NAME					
d. INSURANCE PLAN NAME OR PROGRAM NAME				10d. CLAIM CODES (Designated by NUCC)				6. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/>				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						SIGNED							
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (MM DD YY)						16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM MM DD YY TO MM DD YY)							
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE (NPI 17b)						18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM MM DD YY TO MM DD YY)							
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Niktimvo (axatilimab-csfr), 22 mg/44 mL, IV, 21 mg administered, 1 mg waste, 50881002311													
20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/>													
21. DIAGNOSIS OR NATURE OF ILLNESS, INJURY, OR INFLAMMATION (Relate A-L to service line below (24E))													
22. RESUBMISSION REF. NO.													
23. 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.)													
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 (CPT/HCPCS) E. DIAGNOSIS POINTER F. \$ CHARGES G. DATES OR LIMS H. ICD-10-CM I. ICD-10-PCS J. RENDERING PROVIDER ID.#													
1 N450881002311 ML0.42 J9999 A 1 NPI													
2 N450881002311 ML0.02 J9999 JW A 1 NPI													
3 MM DD YY MM DD YY 11 96413 A 1 NPI													
4													
5													
6													
25. FEDERAL TAX I.D. NUMBER				26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? YES <input type="checkbox"/> NO <input type="checkbox"/>		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.)						32. SERVICE FACILITY LOCATION INFORMATION							
SIGNED						SIGNED							
DATE						DATE							
a. NPI						a. NPI							
b.						b.							

NUCC Instruction Manual available at: [www.nucc.org](http://www.nucc.org)

\*Always refer to specific payer policies as billing requirements for miscellaneous codes may vary by payer.

†Please refer to payer policies as other miscellaneous codes may be required.

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

# 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 with Medicare coverage, 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

For each item, enter a description for the corresponding revenue code. When using a miscellaneous code, include the following\*: *Product Name+N4+11-Digit NDC+ML+Unit Quantity (administered or discarded)*

## Box 44

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

- ▶ Drug - C9399 (Unclassified Drugs or Biologicals)†
- ▶ Modifier - JW (Discarded product should be reported on a separate line with the JW modifier. If no wastage occurs, include the JZ modifier inline with the HCPCS code)
- ▶ Administration - 96413

## Box 45

Enter the date of service

## Box 46

Enter the number of units for each line item. With miscellaneous codes, "1" is typically used, as these codes do not have a specific unit value, but payer requirements may vary

## Box 67

Enter the ICD-10-CM diagnosis code

## Box 80

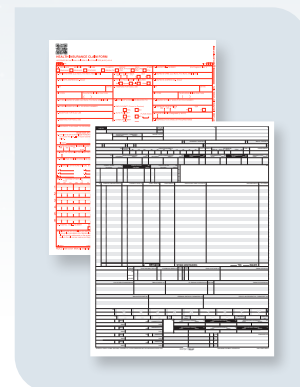
When using a miscellaneous code, include detailed information for proper processing\*: *Drug name, strength, route of administration, dosage administered, amount wasted (if applicable), and NDC*

1	2	3a PAT. CNTL. # b. MED. REC. #	4 TYPE OF BILL
8 PATIENT NAME		9 PATIENT ADDRESS	
10 BIRTHDATE	11 SEX	12 DATE	13 ADMISSION
31 OCCURRENCE DATE		32 OCCURRENCE CODE	33 OCCURRENCE DATE
34 OCCURRENCE DATE		35 OCCURRENCE CODE	36 OCCURRENCE DATE
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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
- ▶ **Check your payer agreements** to ensure you understand the reimbursement for a miscellaneous J-code or C-code, as it may differ from your traditional billing rates
- ▶ **Ensure accurate coding** - refer to page 3 of the Niktimvo Billing & Coding Guide for appropriate codes and modifiers (e.g., CPT®, HCPCS, ICD-10-CM)
  - > Special billing instructions may be required in Box 19 of the CMS-1500 Claim Form, or in Box 80 of the CMS-1450 Claim Form, to ensure the payer has enough information to adjudicate the claim correctly
  - > When using miscellaneous J- and C-codes during the period before Niktimvo is assigned a permanent code, make sure to include all required information in boxes 24A of the CMS-1500 and 43 of the CMS-1450
  - > Refer to the Example Claims Forms on pages 6 and 7 for guidance on how to accurately record appropriate codes and supplemental information
- ▶ **Include correct number** of units administered. When using a miscellaneous code, “1” is typically reported as the code does not have a specific unit value, however, payer requirements may vary. Detailed information should be included in Box 19 of the CMS-1500 or Box 80 of the CMS-1450
- ▶ **Include correct modifier**
  - > JW modifier must be reported on a separate line in the event of wastage
  - > If no product was discarded, report the JZ Modifier on the same line as the HCPCS code
- ▶ **Ensure accuracy** of the following information needed to process the claim:
  - > Correct NDC Format – use 10- or 11-digit format based on payer requirements
  - > Prior Authorization Number, if applicable
- ▶ **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, Call 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.

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**<sup>™</sup>  
(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](#).



# 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](https://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](https://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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