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

Niktimvo closer to home

Support for Local or Home Infusions

Incyte offers a comprehensive range of support services for infusions in the community or through a home infusion provider.

INDICATIONS AND USAGE

Niktimvo™ (axatilimab-csfr) 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.

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.

Please see related and other Important Safety Information on page 14.
Please see Full Prescribing Information for Niktimvo.

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Please see related and other Important Safety Information on page 14.

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Continuity of Care Process

The transplant center care team oversees all treatment decisions and cGVHD management, while infusions are performed by the local provider. Below, ➤ indicates how Incyte can help.

Transplant Center

1. Patient identification and timing of transition

2. Enroll patient in IncyteCARES
- ➤ IncyteCARES can provide support and connection to other support services for eligible patients (see pages 7-8)

3. Identification of local provider
- ➤ Incyte can provide education on continuity of care options and expectations when patients continue care locally (see pages 5-8)

4. Reach out to local provider to initiate coordination of care

Local Provider
(Community Oncology Center or Suite-/Home-Based Infusion)

5. Prepare and receive patient
- ➤ Incyte can provide education on Niktimvo and chronic graft-versus-host disease (cGVHD) (see page 6)

Access and reimbursement
- ➤ Incyte and/or home infusion provider can provide order set guides and access/coverage support (see page 8)

6. Infusion and monitoring
- ➤ Incyte can provide education on all aspects of administration and monitoring (see pages 6, 9-13)

7. Receive laboratory results; if abnormalities, make go/no go decision

Long-term follow-up
- ➤ Incyte can provide ongoing support to help maintain continuity of care

Please see related and other Important Safety Information on page 14.
Please see Full Prescribing Information for Niktimvo.

Transplant Center

Best Practices for Getting Started

Identifying patients suitable for transition to a local provider
- Ensure patients are enrolled in IncyteCARES
- Evaluate patient readiness for transition based on
  - Proximity to transplant center
  - Number of doses received
  - Insurance considerations

Transplant Center and Local Provider

Coordinating the Transition

Transplant Center
- Clear communication of treatment plan, including laboratory parameters
- Transfer of clinical records
- Provide clear expectations about when the local provider should reach out to the transplant center

Local Provider
- Ensure care staff is ready to receive the patient by being trained on Niktimvo and cGVHD and knows when to reach out to the transplant center
- Obtain prior authorization—IncyteCARES can help
- Create order sets to assist in ordering and overall administration/care—Incyte can provide order set guides upon request
- Set up protocols for laboratory monitoring and infusion

Ongoing patient care, management of cGVHD, and coordination are led by the transplant center care team. Successful continuity of care relies on **clear and consistent communication** between the local provider and the transplant center.

cGVHD=chronic graft-versus-host disease.

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Transplant Center

Resources for Finding a Home Infusion/ Infusion Suite Provider

Considerations for selecting a home infusion or infusion suite provider

- Do they specialize in oncolytic products?
- Do they have a trained and experienced nursing staff?
- Do they provide support services such as benefits verification, prior authorization (PA), and patient monitoring?

Options for national providers

Home infusion services may be available through multiple national and local providers. National providers who have indicated experience in oncolytic infusions and have trained nursing staff to assist in home administration include*

Option Care Health
844-624-4584 | OptionCareHealth.com

Coram CVS/Specialty Infusion Services
800-423-1411 | CoramHC.com

KabaFusion
877-577-4844 | KabaFusion.com

Vivo Infusion
855-478-1528 | VivoInfusion.com

*These providers are not affiliated with Incyte and Incyte makes no representations as to the services they provide. Oncolytic home infusion services may be available through other providers.

Visit the National Home Infusion Association's Provider Search Tool at web.nhia.org/search.

Please see related and other Important Safety Information on page 14.
Please see Full Prescribing Information for Niktimvo.

Transplant Center and Local Provider

About Incyte Oncology Clinical Educators

The Incyte Oncology Clinical Educators (OCEs) are tenured nurse clinicians with real-world experience and can provide valuable training on

- **GVHD pathophysiology**
- **Appropriate dosing and administration of Niktimvo**
- **Pre- and post-treatment monitoring**
- **When to reach out to the transplant center**
- **Surveillance for adverse reactions and disease progression that should prompt communication with the transplant center team**
- **Patient/caregiver education**

For additional information/questions on local infusion options, or to speak with an OCE, please contact your account manager for Niktimvo

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IncyteCARES Supports Eligible Patients Through Every Step of Their Journey

Connection to other support services

Our team can provide information about independent organizations that may be able to assist with

- Transportation to medical appointments
- Treatment-related travel cost assistance
- Patient or caregiver support groups
- Emotional, financial, and other counseling services at low or no cost

Reimbursement support

- Insurance benefit verification
- Information about prior authorizations
- Guidance with appealing insurance denials or coverage restrictions

Savings and financial assistance programs*

- Savings on out-of-pocket costs for patients with commercial health insurance coverage†
- Free medication program for patients who are uninsured or underinsured‡

Support and education

An outbound welcome call from an IncyteCARES for Niktimvo representative will inform patients about their coverage for Niktimvo and available resources that may assist them during treatment

IncyteCARES is committed to supporting patients throughout the transition process and while they are receiving treatment with Niktimvo from a local provider or at home. The Niktimvo call center is available at <<1-855-452-5234>>, Monday through Friday, 8 AM–8 PM ET

*Patients must meet eligibility requirements and terms and conditions, available at <<HCP.IncyteCARES.com/oncology-hematology/niktimvo>>.

†<<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.>>

‡Free product is offered to eligible patients without any purchase contingency or other obligation. Terms and conditions apply. Terms of these programs may change at any time. Patients who are enrolled in an Alternate Funding Program (AFP) are not eligible to receive free drug.

Please see related and other Important Safety Information on page 14.

Please see Full Prescribing Information for Niktimvo.

How to Enroll Patients in IncyteCARES

Print and fax an IncyteCARES for Niktimvo Enrollment Form to enroll your eligible patients

Visit

<<hcp.incytecares.com/pdf/niktimvo-enrollment-form.pdf>> to complete the enrollment form online

Download and fax

the completed form to 1-866-870-6241

IncyteCARES can support transplant centers in assessing alternate site-of-care options for treatment by providing

- Information on alternate site-of-care options, including providers, services, and coverage maps
- Benefits investigations to discover whether home infusion may be an option for the patient
- Benefits verifications to include information regarding patients' healthcare plan prior authorization (PA) requirements

Field Access Managers Can Help

Field Access Managers are an extension of IncyteCARES and can provide

- Information on IncyteCARES
- For transplant centers, information on transitioning patients to a different site of care
- For local providers, billing and coding support
- Information and guidance for your staff, should your office encounter any access barriers (eg, delays, denials)

To speak with a Field Access Manager, please contact your account manager for Niktimvo

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Local Provider

Preadministration Recommendations for Niktimvo[1,2]

Step-by-step instructions

1 Confirm the following:

- Previous infusion was 2 weeks prior
- No disease progression or unacceptable toxicity

2 Confirm patient weight

- Verify the patient weighs at least 40 kg
- For patients weighing more than 116 kg, the maximum dose of Niktimvo is 35 mg

3 If laboratory monitoring is required, check results

- Ensure all recommended laboratory results are present:
  - ☐ ALP, ALT, AST
  - ☐ CPK
  - ☐ Amylase
  - ☐ Lipase

Note: Transient increases in serum enzymes are consistent with the known effect of CSF-1R inhibition on macrophage clearance.

4 Interpret results

- If ≥ Grade 3 enzyme elevations:
  - ☐ No organ damage and asymptomatic, proceed to infusion
  - ☐ Organ damage or symptomatic, do not infuse (see "NO-GO") and follow guidelines

NO-GO
Do not infuse if:

- Labs show ≥ Grade 3 abnormalities with evidence of end-organ damage
- Patient has new or worsening symptoms
- Prior adverse reaction has not resolved
- Infusion is delayed > 4 weeks from planned schedule
- Contact the patient's transplant team if the patient is not appropriate for infusion or clinical uncertainty exists

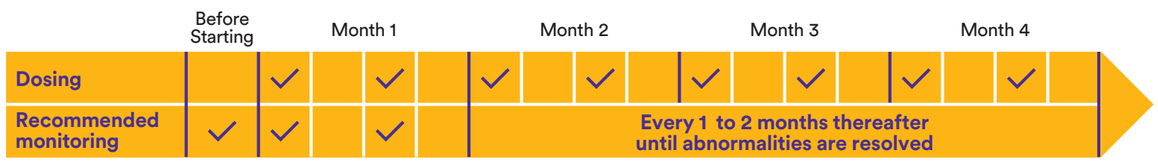
Permanently discontinue Niktimvo if:

- In ≥ Grade 3 severity, for elevation of CPK, amylase, or lipase if diagnostic evaluation results show evidence of end-organ damage
- In symptomatic ≥ Grade 3 severity, for elevation of CPK, amylase, or lipase

Recommended Niktimvo dosage modifications for adverse reactions are found on page 12.

Note: Monitor bone growth and development in pediatric patients. This is based on findings of thickening of the growth plate and metaphysis and/or degeneration of the growth plate in the femur in animals.

Continue administering Niktimvo unless there is disease progression or unacceptable toxicity.



ALP=alkaline phosphatase; ALT=alanine aminotransferase; AST=aspartate aminotransferase; CPK=creatine phosphokinase.

Please see related and other Important Safety Information on page 14.
Please see Full Prescribing Information for Niktimvo.

Local Provider

Preparing Niktimvo for Administration

Niktimvo is available in single-dose vial sizes[1]

- 9 mg/0.18 mL (NDC 50881-034-12)
- 22 mg/0.44 mL (NDC 50881-023-11)

For illustrative purposes only.

Preparing Niktimvo[1]

Use aseptic technique to prepare Niktimvo. Visually inspect the vial for particulate matter and discoloration prior to dilution. Niktimvo is a slightly opalescent, pale brownish yellow solution. Discard the vial if the solution is cloudy, discolored, or contains visible particles. Do not shake the vial.

Determine the dose and total volume of Niktimvo solution needed. Recommended starting dosage is 0.3 mg/kg (maximum 35 mg) intravenously (IV) every 2 weeks. Each mL of Niktimvo contains 50 mg of axatilimab-csfr.

Dilution[1]

Using aseptic technique, withdraw the calculated volume of Niktimvo solution from the vial. Discard vial with any unused portion.

Add Niktimvo into an IV infusion bag made of polyvinyl chloride (PVC), polyolefin, polyolefin with polyamide, or ethylene vinyl acetate (EVA) containing 0.9% Sodium Chloride Injection to achieve a final concentration between the range of 0.24 mg/mL and 0.75 mg/mL.

Mix diluted solution by gentle inversion. Do not shake.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The diluted solution is a clear to slightly opalescent, colorless solution that may contain trace amounts of translucent to white particles. Discard if the solution is cloudy, discolored, or contains extraneous particulate matter other than trace amounts of translucent to white particles.

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Administration of Niktimvo[1]

Administer diluted Niktimvo solution by IV infusion over 30 minutes.

If the patient has a history of infusion-related reactions with Niktimvo, infuse at 50% of the prior infusion rate and premedicate with

- Antihistamine
- Antipyretic

Use a dedicated infusion line that includes a sterile, low-protein binding 0.2-micron in-line or add-on polyethersulfone (PES) filter.

Do not co-administer other drugs through the same infusion line.

Confirm no signs of active infusion-related adverse reactions: fever, chills, rash, flushing, dyspnea, and hypertension.

After administration, flush the infusion line with 0.9% Sodium Chloride Injection.

Please see related and other Important Safety Information on page 14.
Please see Full Prescribing Information for Niktimvo.

Recommended Niktimvo Dosage Modifications for Adverse Reactions[1]

Adverse reaction	Severity[a]	Dosage modification
Infusion-related reactions	Grade 1 or 2	• Temporarily interrupt the infusion until resolution or decrease infusion rate by 50% • Initiate symptomatic treatment (eg, antihistamines and antipyretics) • For subsequent infusions, premedicate and resume the infusion at 50% of the prior infusion rate
	Grade 3 or 4	Permanently discontinue Niktimvo.
Elevation of AST or ALT (on the day of dosing)	Grade 3 with total bilirubin ≤ Grade 1	Withhold Niktimvo until recovery to Grade 2, then resume Niktimvo at 0.2 mg/kg (maximum 23 mg) every 2 weeks.
Elevation of AST or ALT (regardless of the time of the reaction)	ALT or AST ≥ 3 × ULN with total bilirubin ≥ 2 × ULN and ALP < 2 × ULN	Withhold Niktimvo and investigate for drug-induced liver injury. If confirmed, permanently discontinue Niktimvo.
	Grade 4	Permanently discontinue Niktimvo.
Elevation of CPK, amylase, or lipase	≥ Grade 3	• If diagnostic evaluation results show no evidence of end-organ damage, continue Niktimvo without dose reduction • If diagnostic evaluation results show evidence of end-organ damage, permanently discontinue Niktimvo
	Symptomatic ≥ Grade 3	Permanently discontinue Niktimvo.
Other nonhematologic adverse reactions	Grade 3	Withhold Niktimvo until recovery to Grade 2: • If delayed by ≤ 4 weeks from the planned infusion, resume Niktimvo at 0.2 mg/kg (maximum 23 mg) every 2 weeks • If delayed by > 4 weeks from the planned infusion, permanently discontinue Niktimvo
	Grade 4	Permanently discontinue Niktimvo.

[a]Graded per National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.
ALP=alkaline phosphatase; ALT=alanine aminotransferase; AST=aspartate aminotransferase; CPK=creatine phosphokinase; ULN=upper limit of normal.

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Local Provider

NCI CTCAE Version 5.0 Grading for Adverse Reactions[3]

Adverse reaction	Grade 1	Grade 2	Grade 3	Grade 4
Infusion-related reactions	Mild transient reaction; infusion interruption not indicated; intervention not indicated	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (eg, antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for ≤ 24 hours	Prolonged (eg, not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae	Life-threatening consequences; urgent intervention indicated
Elevation of AST or ALT (on the day of dosing)				
• **Normal baseline**	> ULN - 3.0 × ULN	> 3.0 - 5.0 × ULN	> 5.0 - 20.0 × ULN	> 20.0 × ULN
• **Abnormal baseline**	1.5 - 3.0 × baseline	> 3.0 - 5.0 × baseline	> 5.0 - 20.0 × baseline	> 20.0 × baseline
Elevation of CPK	> ULN - 2.5 × ULN	> 2.5 × ULN - 5 × ULN	> 5 × ULN - 10 × ULN	> 10 × ULN
Elevation of amylase	> ULN - 1.5 × ULN	> 1.5 - 2.0 × ULN OR > 2.0 - 5.0 × ULN and asymptomatic	> 2.0 - 5.0 × ULN with signs or symptoms OR > 5.0 × ULN and asymptomatic	> 5.0 × ULN and with signs or symptoms
Elevation of lipase	> ULN - 1.5 × ULN	> 1.5 - 2.0 × ULN OR > 2.0 - 5.0 × ULN and asymptomatic	> 2.0 - 5.0 × ULN with signs or symptoms OR > 5.0 × ULN and asymptomatic	> 5.0 × ULN and with signs or symptoms

ALT=alanine aminotransferase; AST=aspartate aminotransferase; CPK=creatine phosphokinase; CTCAE=Common Terminology Criteria for Adverse Events; IV=intravenous; NCI=National Cancer Institute; NSAID=nonsteroidal anti-inflammatory drug; ULN=upper limit of normal.

Please see related and other Important Safety Information on page 14.
Please see Full Prescribing Information for Niktimvo.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Niktimvo™ (axatilimab-csfr) 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.

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.

The most common (≥ 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.

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.

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.

References: 1. Niktimvo Prescribing Information. Wilmington, DE: Incyte Corporation. **2.** Data on file. Incyte Corporation. Wilmington, DE. **3.** National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0. Published: November 27, 2017.

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Support for Administration of Niktimvo Closer to Home

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

Incyte can help with transitions from transplant centers to local providers by

EDUCATING
on dosing and administration of Niktimvo and on cGVHD

ASSISTING
with access, reimbursement, and patient support resources for eligible patients

PROVIDING
options for local infusion

To get started, contact your account manager for Niktimvo

Please see related and other Important Safety Information on page 14.
Please see Full Prescribing Information for Niktimvo.