

Niktimvo closer to home

Resources for Local or Home Infusions

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

INDICATIONS AND USAGE

NiktimvoTM (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 9](#).

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

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Continuity of Care Process

The transplant center care team oversees all treatment decisions and cGVHD management.

Infusions are performed by the local provider, but early, frequent, and clear communication is essential for continuity of care.

Who can help with continuity of care?

AM Account Managers

The lead coordinator in the continuity of care process who identifies when to pull in different team members

NN IncyteCARES Nurse Navigators

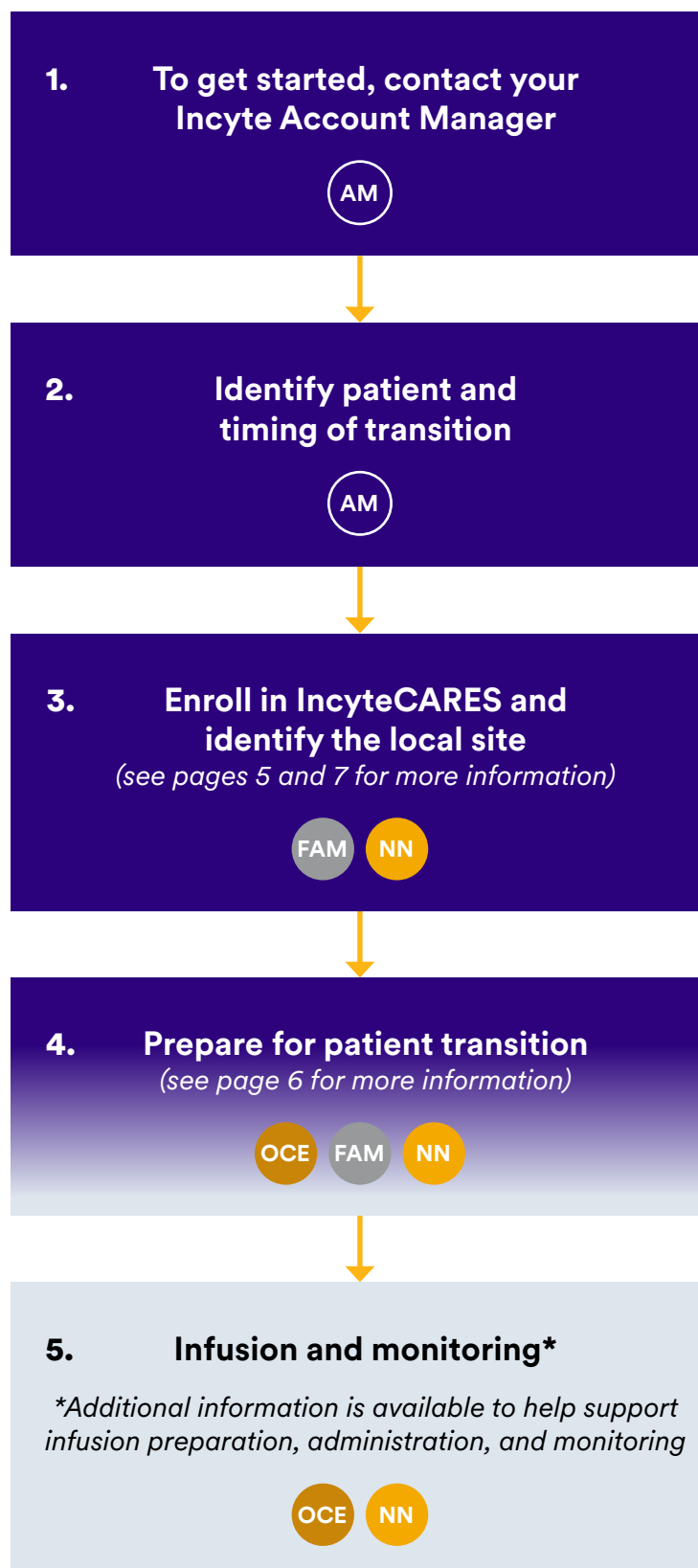
Trained experts who help patients stay engaged and supported by providing structured outreach, symptom tracking guidance, and access support

OCE Oncology Clinical Educators (OCEs)

Tenured clinicians who educate centers on cGVHD, infusion of Niktimvo, and monitoring

FAM Field Access Managers (FAMs)

Specialists who assist eligible patients with access and support during treatment with Niktimvo. See page 7 for more information.



cGVHD=chronic graft-versus-host disease.

Please see related and other Important Safety Information on [page 9](#).
Please [click here](#) for Full Prescribing Information for Niktimvo.

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

Coordinating the Transition

Successful continuity of care relies on early, clear, and consistent communication between the transplant center and local provider.

Transplant Center

Patient identification



- Transition suitability may be based on
 - Ability to come in every 2 weeks
 - Trends in laboratory values
 - Disease stability
 - Insurance considerations
- Identify local/home infusion provider to begin coordination

Preparing for transition



- Share treatment plan and acceptable laboratory values if ongoing monitoring is required
- Transfer clinical records, including organ involvement, medications, and comorbidities
- Discuss when and how the local provider should contact the transplant center

Long-term follow-up



- Ongoing patient care, management of cGVHD, and coordination
- Make go/no-go decision if laboratory values outside of specified parameters

Local/Home Infusion Provider

Receiving the patient



- Receive training on cGVHD and Niktimvo
- Obtain prior authorization
- Create order sets and protocols

Administration of Niktimvo



- Obtain laboratory values if ongoing monitoring is required
 - Transplant center can make go/no-go decision if laboratory values are outside specified parameters
- Infusion of Niktimvo
- Monitor for infusion-related reactions

Long-term follow-up



- Stay in frequent contact with the transplant center
- Reach out for any worsening or clinical uncertainty

cGVHD=chronic graft-versus-host disease.

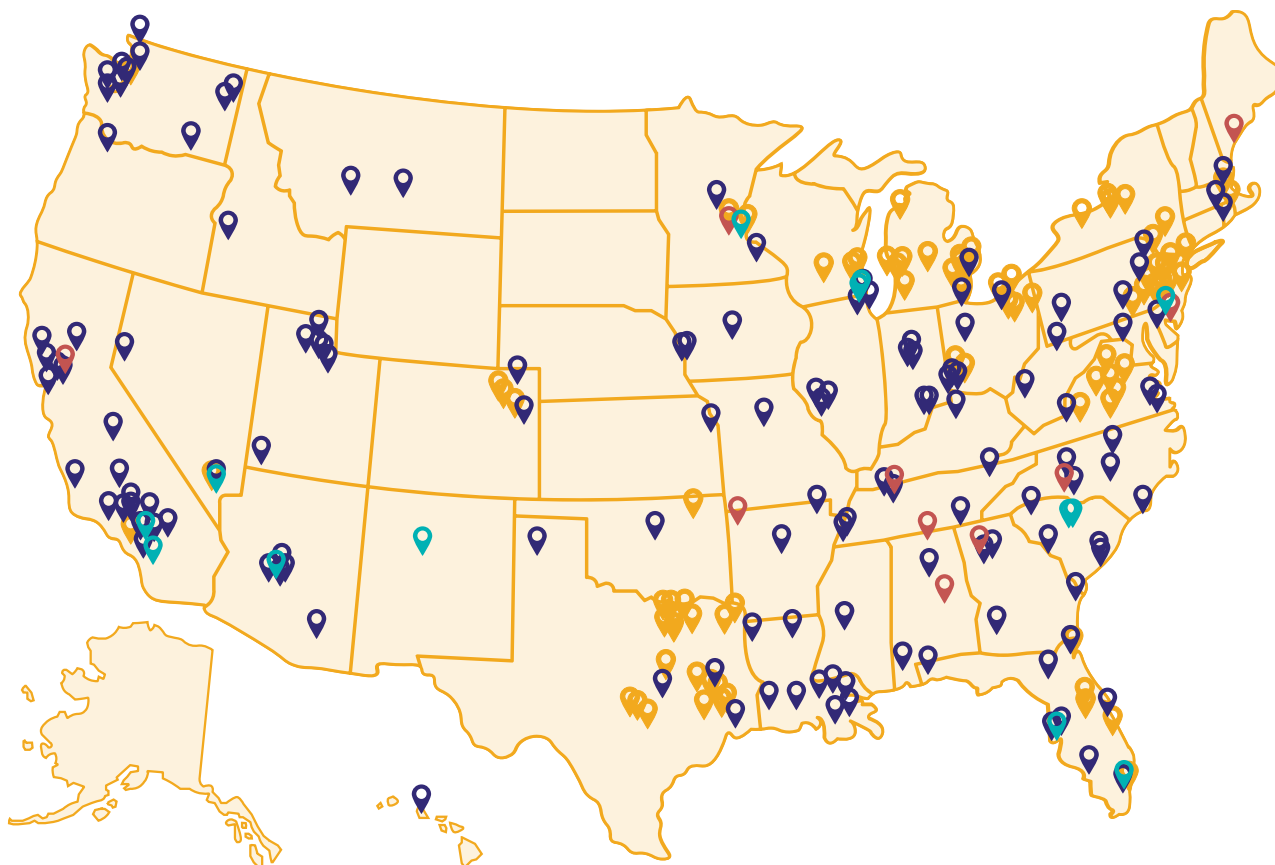
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Resources for Finding a Home Infusion/ Infusion Suite Provider

The Infusion Site Locator is now live!

Home infusion is covered in all 50 states, with satellite infusion centers located in 47 states.



Nationwide Locations

-  Option Care
-  KabaFusion – except ND, SD, MT, AK, HI
-  Vivo Infusion
-  Coram CVS

Nationwide Home Infusion Coverage

-  All 50 states

While Incyte has attempted to provide a complete listing of sites that are qualified to offer Niktimvo infusions, this list may not be complete and some provider statuses may have changed. Incyte does not endorse, recommend, or guarantee the quality of care for any healthcare provider. Nor does Incyte guarantee that the information on this site is current. Please contact the infusion site directly to get the most up-to-date information. Please consult the NHIA or NICA for a complete list of home and local infusion locations.



Scan to access the infusion site locator or [click here](#)

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IncyteCARES Supports Eligible Patients With a Dedicated 1:1 Nurse Navigator



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

Patients will receive a welcome call from an IncyteCARES representative to review their coverage and connect them with available support resources

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.

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How to Enroll Patients in IncyteCARES

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



Scan the QR code to complete the enrollment form online, or visit
<<hcp.incytecares.com/pdf/niktimvo-enrollment-form.pdf>>

Download and fax the completed form to 1-866-870-6241

When assessing alternate site-of-care options for patients, IncyteCARES can provide:

- 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

FAMs can help

FAMs 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)

FAMs are an extension of IncyteCARES and can provide support on enrollment and reimbursement. To speak with a FAM, please contact your account manager for Niktimvo

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Support for Administration of Niktimvo Closer to Home

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



EDUCATING

on cGVHD, Niktimvo, and appropriate dosing and administration
Contact your local OCE for education on cGVHD



ASSISTING

with access, reimbursement, and patient support resources for eligible patients
Contact your local FAM for enrollment and reimbursement support



PROVIDING

information on options for local/home infusion providers

Additional information is available upon request.

To get started, contact your account manager for Niktimvo

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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 [click here](#) for Full Prescribing Information for Niktimvo.



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