

What to expect when starting Niktimvo



INDICATIONS AND USAGE

Niktimvo[™] (axatilimab-csfr) is a prescription medicine used to treat adults and children who weigh at least 88.2 pounds (40 kg) with chronic graft-versus-host disease (cGVHD) after receiving at least 2 prior treatments (systemic therapy) and they did not work.

It is not known if Niktimvo is safe and effective in adults and children weighing less than 88.2 pounds (40 kg).

Please see [Important Safety Information](#) and [Full Prescribing Information](#), which includes a more complete discussion of the risks associated with Niktimvo.

What makes Niktimvo™ (axatilimab-csfr) different?

Niktimvo is the FIRST AND ONLY treatment to block the CSF-1 receptor in chronic graft-versus-host disease (GVHD)

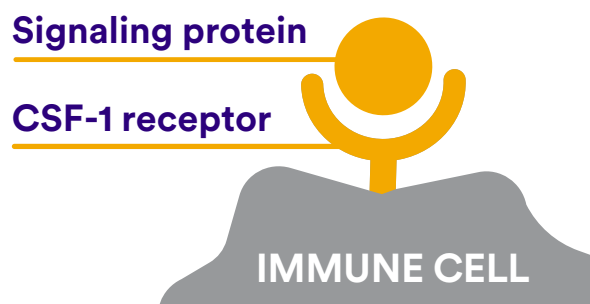
Other treatments you may have tried target different immune cells, such as T cells and/or B cells.

Why does the CSF-1 receptor matter?

The CSF-1 receptor is located on the surface of certain immune cells.

When a signaling protein binds to the CSF-1 receptor, it sends signals that increase the activity of immune cells, leading to inflammation and fibrosis.

Inflammation and fibrosis are 2 key contributors to chronic GVHD symptoms.



Increased immune cell activity leads to inflammation and fibrosis

Inflammation: Part of the body's immune response to fight off infection or heal damaged tissue. Chronic inflammation is an abnormal immune response that can damage cells and organs over time.

Fibrosis: The growth of scar tissue in the body.

CSF-1=colony stimulating factor-1.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of Niktimvo?

Niktimvo may cause serious side effects, including:

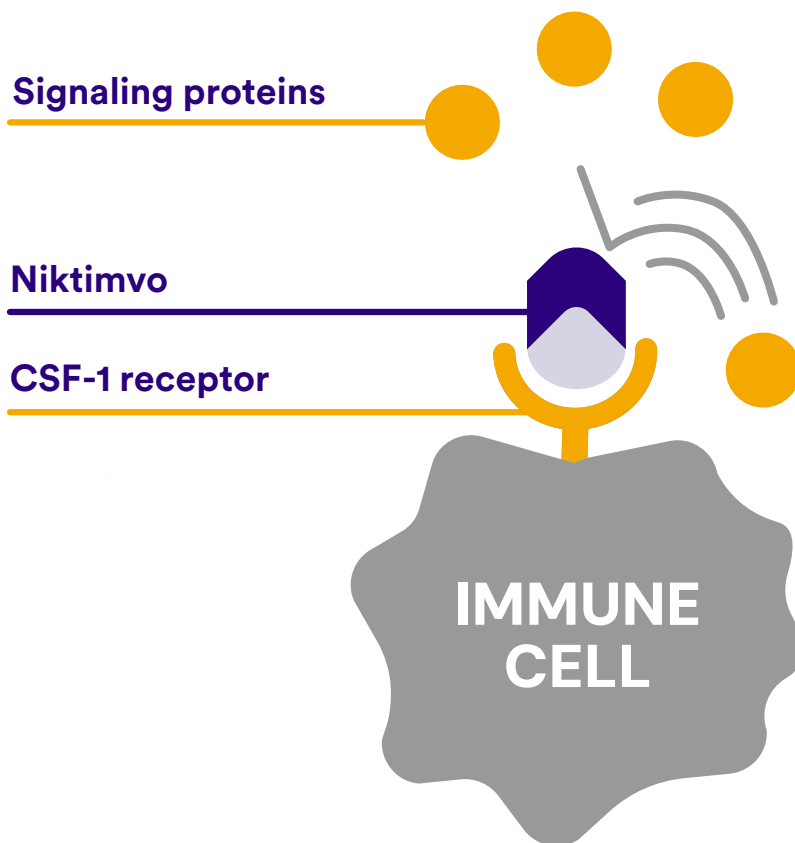
Infusion-related reactions. Infusion-related reactions are common with Niktimvo and can be serious. Your healthcare provider will monitor you for infusion-related reactions during your treatment. If you have a reaction, your healthcare provider may temporarily or completely stop your treatment with Niktimvo. Tell your healthcare provider right away if you have fever, chills, rash, flushing, shortness of breath, trouble breathing, nausea, vomiting, or symptoms of high blood pressure such as chest pain, headaches, or blurred vision during an infusion of Niktimvo.

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

Niktimvo™ (axatilimab-csfr) works differently to treat chronic GVHD

Niktimvo blocks the CSF-1 receptor to help reduce inflammation and fibrosis in chronic GVHD



Niktimvo blocks signaling proteins, potentially addressing both inflammation and fibrosis

This is how Niktimvo was shown to work in lab studies.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of Niktimvo include:

- infections
- increased blood level of liver enzymes
- decreased blood level of phosphate
- low red blood cell count (anemia)
- muscle, bone, or joint pain

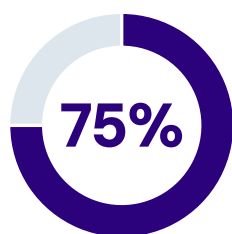
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Niktimvo™ (axatilimab-csfr) was shown to make a meaningful difference

Niktimvo was studied in 79 people who had received a stem cell transplant, received **at least 2 prior treatments for chronic GVHD**, and weighed at least 88.2 pounds (40 kg).

People in the study were given Niktimvo 0.3 mg/kg every 2 weeks. The main goal of the study was to see how many people saw a response to treatment through 24 weeks.



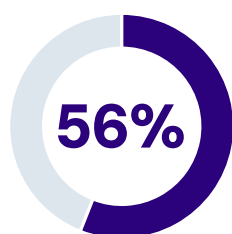
of people (59 out of 79)

experienced some improvement in their chronic GVHD

In the clinical trial, **all people who saw improvement achieved a partial response**, meaning they saw improvement in at least one affected area without worsening signs or symptoms in other areas.

The median time to first response was 1.5 months (6 weeks)

The time to first response ranged from 4 weeks to 22 weeks.



of people (44 out of 79)

reported being less bothered by their chronic GVHD symptoms in an exploratory analysis of the study

This was measured using a patient questionnaire called the modified Lee Symptom Scale.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of Niktimvo include (continued):

- increased blood level of pancreatic enzymes
- low energy
- increased blood level of calcium
- increased blood level of a muscle enzyme
- increased blood level of a bone enzyme
- nausea
- headache
- diarrhea
- cough
- fever
- shortness of breath

These are not all the possible side effects of Niktimvo.
Call your doctor for medical advice about side effects.

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Niktimvo™ (axatilimab-csfr) was studied in people with multi-organ disease



Eyes



Lungs



Joints and muscles



Mouth



Liver



Skin



Esophagus



Digestive tract

Helpful words to know

Exploratory analysis: An analysis that looks at additional information from the study to understand people's experiences. This was not a main measure of how well Niktimvo worked in the study.

Median: The number in the middle of a group of numbers lined up from lowest to highest. It's not the same as an average.

Modified Lee Symptom Scale: This measured patient-reported symptom bother using a patient questionnaire. Patients were counted as "less bothered" when they reported a 7+ point improvement from the start of the study to week 24.

IMPORTANT SAFETY INFORMATION (continued)

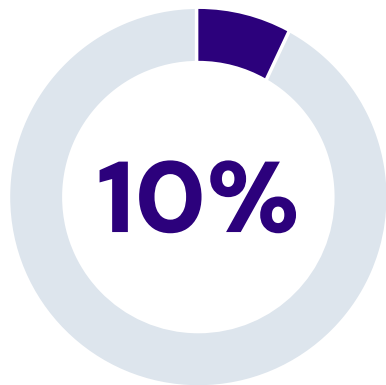
Before receiving Niktimvo, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems.
- are pregnant or plan to become pregnant. Niktimvo may harm your unborn baby.

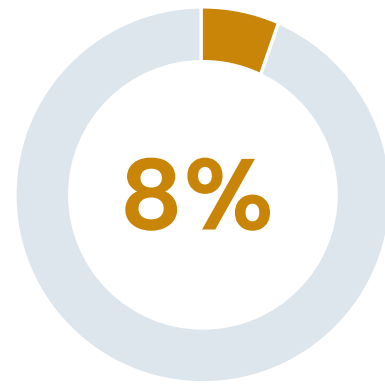
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Some people stopped taking or reduced their dose of Niktimvo™ (axatilimab-csfr) because of side effects



10% of people
stopped taking Niktimvo
because of side effects



8% of people
reduced their dose of Niktimvo
because of side effects

It's important to keep an eye out for any possible side effects while taking Niktimvo and report them to your doctor right away.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving Niktimvo, tell your healthcare provider about all of your medical conditions, including if you (continued):

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with Niktimvo.
- You should use an effective method of birth control during your treatment and for 30 days after your last dose of Niktimvo. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Niktimvo.

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Receiving treatment with Niktimvo™ (axatilimab-csfr)



How will I receive Niktimvo?

- Niktimvo is given to you as an intravenous (IV) infusion at your doctor's office or infusion center
- Infusion-related reactions may occur. Before you receive each Niktimvo infusion, your doctor may give you medications like diphenhydramine (ie, Benadryl) or acetaminophen (ie, Tylenol) to help prevent infusion-related reactions



How long does each infusion last?

Each IV infusion of Niktimvo lasts about 30 minutes.



How often will I need to receive Niktimvo?

- Niktimvo is given once every 2 weeks to start
- Your doctor will decide how many treatments you will need
- Your doctor will do blood tests to check you for side effects



What is my starting dose of Niktimvo?

Your starting dose is based on your weight.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving Niktimvo, tell your healthcare provider about all of your medical conditions, including if you (continued):

- are breastfeeding or plan to breastfeed. It is not known if Niktimvo passes into your breast milk. Do not breastfeed during treatment and for 30 days after your last dose of Niktimvo.

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Receiving Niktimvo™ (axatilimab-csfr) closer to home

Some patients may be able to receive Niktimvo at an alternate infusion site, sometimes closer to home.

Your doctor can help determine which setting is appropriate for your treatment.



Bone marrow transplant center

- Niktimvo infusions may be given at the same location where you received your bone marrow transplant. Your doctor can help determine if continuing treatment there is appropriate for your care
- May be an option for people who need additional monitoring or support while receiving treatment



Local infusion center or suite

- Infusion centers and suites are settings dedicated to infusions and can be freestanding clinics or part of hospitals or doctors' offices
- May be an option for people whose care team identifies an appropriate local infusion setting



Your home

- A highly skilled infusion provider will administer treatment in your home
- May be an option for people who don't need additional monitoring or support during treatment. Your doctor will determine whether at-home infusions are appropriate for you



To learn more about where you may be able to receive Niktimvo, talk with your doctor

IMPORTANT SAFETY INFORMATION (continued)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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Ask about receiving Niktimvo™ (axatilimab-csfr) closer to home

Bring up infusion location options at your next doctor's visit. Your care team can help determine where you may be able to receive Niktimvo.

Writing down a few questions ahead of time can help you feel ready to discuss your options.



Write it down

Use the space on the following pages to make a list of questions and concerns you want to discuss regarding where you receive your infusions. **Bring this with you to your next appointment.**

Share what matters to you

- Talk to your doctor about any concerns you have about starting infusion therapy, such as:
 - Travel time to and from treatment
 - Appointment timing and scheduling
 - How treatment visits fit into your routine
- Be open about what matters to you so your care team can help guide treatment planning and provide infusion location options

Ask about Niktimvo infusion location options

- At your next appointment, ask your care team about where you may be able to receive Niktimvo and what steps come next

Ask about patient support through IncyteCARES

- If you and your doctor decide an alternate infusion location may be appropriate, ask what support may be available through IncyteCARES

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Start here for patient support

If you and your doctor determine that a local or at-home infusion location may be appropriate for you, IncyteCARES may be able to help you and your care team navigate next steps.

(IncyteCARES) may be able to support eligible patients by:

- ✓ Educating your care team on alternate infusion location options
- ✓ Helping you and your care team navigate insurance coverage, prior authorization, and treatment-related support



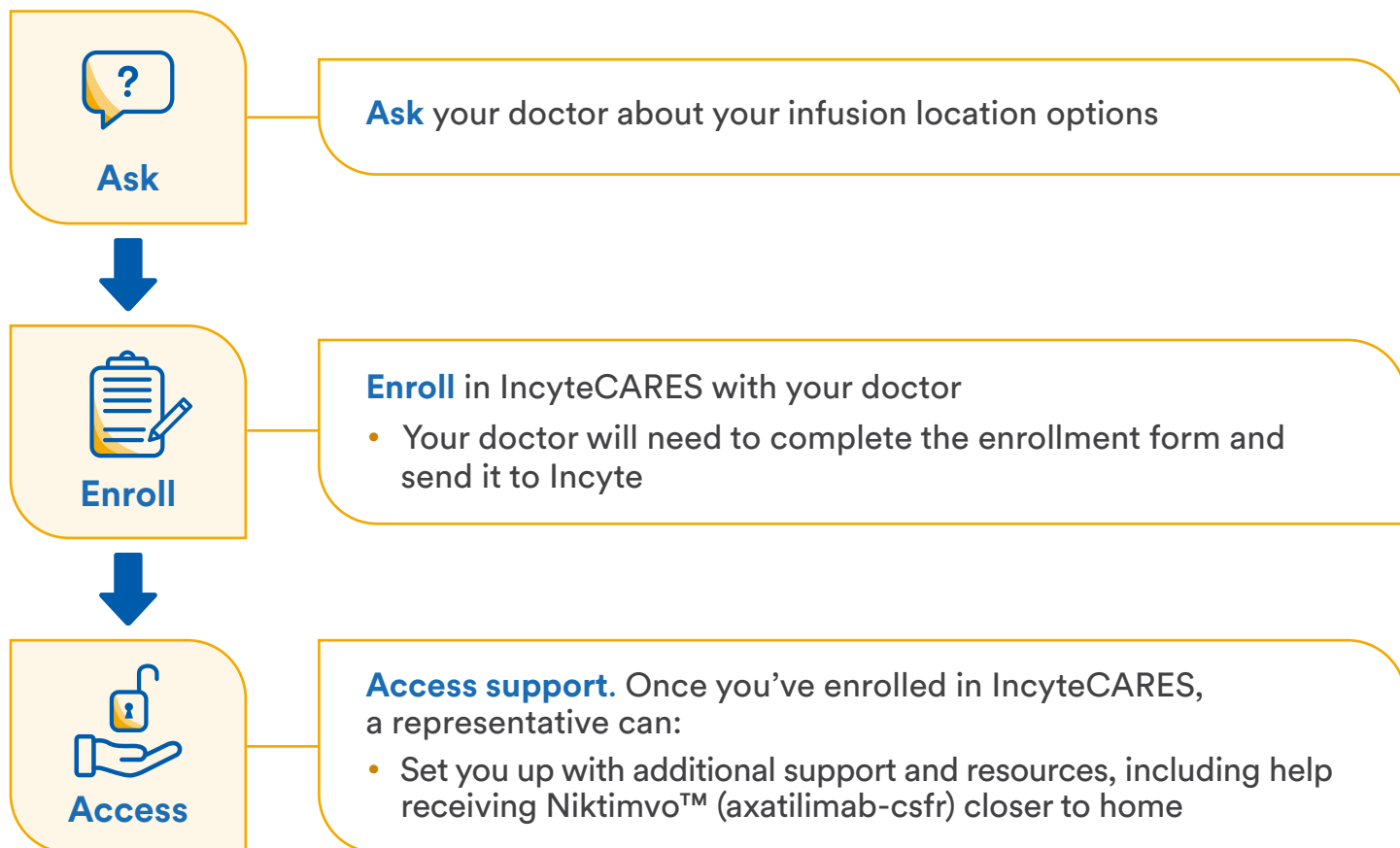
Use this search tool to find local or at-home infusion providers for your care team to consider

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Added support for getting started

IncyteCARES can help you get started at your infusion location



Our IncyteCARES call center is available to answer your questions and offer additional information and support during your treatment.

Call 1-855-452-5234, Monday through Friday, 8 AM–8 PM ET.

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Questions to ask your doctor

It's important to talk with your doctor and ask any questions you may have about chronic GVHD and your treatment with Niktimvo™ (axatilimab-csfr).

Before your next appointment, take a moment to think about anything you would like to discuss with your doctor and write down any questions or concerns.

The following questions may help get you started

How should I prepare for my Niktimvo infusions?

What kind of lab work will I need? How often?

What kind of monitoring is done with Niktimvo? How often?

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Questions to ask your doctor (continued)

What’s the best way to track my progress?

What side effects should I watch out for and how soon should I contact you about them?

Additional notes

Please see [Important Safety Information](#) and [Full Prescribing Information](#), which includes a more complete discussion of the risks associated with Niktimvo.



IMPORTANT SAFETY INFORMATION

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- increased blood level of liver enzymes
- decreased blood level of phosphate
- low red blood cell count (anemia)
- muscle, bone, or joint pain
- increased blood level of pancreatic enzymes
- low energy
- increased blood level of calcium
- increased blood level of a muscle enzyme
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- diarrhea
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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see the Full Prescribing Information, which includes a more complete discussion of the risks associated with Niktimvo.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call **1-800-FDA-1088**.

You may also report side effects to Incyte Medical Information at 1-855-463-3463.



Meaningful relief from chronic GVHD is possible

Niktimvo™ (axatilimab-csfr) takes a different approach to stay one step ahead of chronic GVHD

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



IncyteCARES can help with access to and support for your treatment.

Ask your doctor about enrollment.



Scan the code to learn more
or visit [IncyteCARES.com](https://www.IncyteCARES.com)



**Or call 1-855-452-5234, Monday through Friday,
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