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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 6, 2024
Subject:	Niktimvo	**Page:**	1 of 4

Last Review Date: March 6, 2026

Niktimvo

Description

Niktimvo (axatilimab-csfr)

Background
Niktimvo (axatilimab-csfr) is a monoclonal antibody that binds to colony stimulating factor-1 receptors (CSF-1R) expressed on monocytes and macrophages. Blocking CSF-1R with Niktimvo reduces the levels of these circulating proinflammatory and profibrotic monocytes and monocyte-derived macrophages, as demonstrated by a reduction of nonclassical monocyte counts in nonclinical studies with Niktimvo and inhibits the activity of macrophages in tissues (1).

Regulatory Status
FDA-approved 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 (1).

Niktimvo carries warnings for infusion-related reactions and embryo-fetal toxicity. Interrupt or slow the rate of infusion or permanently discontinue Niktimvo based on severity of reaction. 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 (1).

The safety and effectiveness of Niktimvo in pediatric patients weighing less than 40 kg have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Niktimvo may be considered **medically necessary** if the conditions indicated below are met.

Niktimvo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Chronic graft-versus-host disease (cGVHD)
    a. Patient has received at least two prior lines of systemic therapy

AND ALL of the following:

a. Patient weight ≥ 40 kg
b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Niktimvo and for 30 days after the last dose

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

1. Chronic graft-versus-host disease (cGVHD)
    a. **NO** disease progression or unacceptable toxicity

AND ALL of the following:

a. Patient weight ≥ 40 kg

b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Niktimvo and for 30 days after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 vials per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Niktimvo (axatilimab-csfr) is a colony stimulating factor-1 receptor-blocking antibody indicated for the treatment of patients with chronic graft-versus-host disease who have received at least two prior lines of systemic treatment. Niktimvo carries warnings for infusion-related reactions and embryo-fetal toxicity. The safety and effectiveness of Niktimvo in pediatric patients weighing less than 40 kg have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Niktimvo while maintaining optimal therapeutic outcomes.

References

1. Niktimvo [package insert]. Wilmington, DE: Incyte Corporation; January 2025.
2. NCCN Drugs & Biologics Compendium® Axatilimab-csfr 2026. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2026.

Policy History

Date	Action

September 2024	Addition to PA
June 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.