# Medical Policy:

## Niktimvo (axatilimab-csfr) Intravenous

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.433 | March 24, 2025 | March 24, 2025 |



## Definitions

Niktimvo is 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.

## Length of Authorization

Coverage will be provided for 6 months and may be renewed.

## Dosing Limits [Medical Benefit]

**Max Units (per dose and over time) [HCPCS Unit]:**

• 50 mg every 2 weeks

## Guideline

## Applicable Procedure Codes

### I. INITIAL CRITERIA

**1. <u>Chronic Graft versus Host Disease (cGVHD)</u>**

A. Patient is at least 6 years of age; **AND**

B. Patient weighs at least 40 kg; **AND**
C. Patient has recurrent or refractory disease; **AND**
D. Used as a single agent or in conjunction with systemic steroids, calcineurin inhibitors (e.g., cyclosporin, etc.) or mTOR inhibitors (e.g., sirolimus, everolimus, etc.); **AND**
E. Patient is post-allogeneic stem cell transplant (generally 3 or more months); **AND**
F. Patient has failed two or more previous lines of systemic therapy for the treatment of cGVHD

**II. RENEWAL CRITERIA**

Coverage can be renewed based on the following criteria:

A. Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Criteria; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion related reactions, etc.; **AND**
C. Response to therapy with an improvement in **ONE** or more of the following:
i. Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.); **OR**
ii. Patient-reported symptoms (e.g., Lee Symptom Scale, etc.)

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J9038 | Injection, axatilimab-csfr, 0.1 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 50881-0023-11 | Niktimvo 22 mg/0.44mL |
| 50881-0034-12 | Niktimvo 9 mg/0.18mL |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| D89.811 | Chronic Graft-Versus-Host Disease |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 03/24/2025 | New Policy |

## References

1. Niktimvo™ intravenous infusion [prescribing information]. Wilmington, DE: Incyte; August 2024.