

Medical Policy:

Niktimvo (axatilimab-csfr) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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. Chronic Graft versus Host Disease (cGVHD)

- 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.