Niktimvo™ (axatilimab-csfr)
(Intravenous)

Document Number: IC-0767

Last Review Date: 09/05/2024
Date of Origin: 09/05/2024
Dates Reviewed: 09/2024

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Niktimvo 50 mg/mL solution in SDV: 1 vial every 2 weeks

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

- 50 mg every 2 weeks

III. Initial Approval Criteria [1]

Coverage for is provided for treatment of the following conditions:

- Patient is at least 6 years of age; **AND**

Universal Criteria [1]

- Patient weighs at least 40 kg; **AND**

Chronic Graft versus Host Disease (cGVHD) † Φ [1-4]

- Patient has recurrent or refractory disease; **AND**
- 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**
- Patient is post-allogeneic stem cell transplant (generally 3 or more months); **AND**
- Patient has failed two or more previous lines of systemic therapy for the treatment of cGVHD

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,5]

Coverage can be renewed based on the following criteria:

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

V. Dosage/Administration [1,3,7,21-23,25]

Indication	Dose
cGVHD	For patients weighing at least 40 kg, administer Niktimvo 0.3 mg/kg, up to a maximum dose of 35 mg, as an intravenous infusion over 30 minutes every 2 weeks until progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 — Unclassified biologics

NDC:

- Niktimvo 50 mg/mL solution in a single-dose vial: 50881-0012-xx

VII. References

1. Niktimvo [package insert]. Wilmington, DE; Incyte, Inc. August 2024. Accessed August 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for axatilimab. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Hematopoietic Cell Transplantation (HCT) Version 1.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of

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4. Wolff D, Cutler C, Lee SJ, et al. Safety and Efficacy of Axatilimab at 3 Different Doses in Patients with Chronic Graft-Versus-Host Disease (AGAVE-201). Blood, Volume 142, Supplement 1, 2023, Page 1, ISSN 0006-4971, https://doi.org/10.1182/blood-2023-186963..
5. Lee SJ, Wolff D, Kitko C, et al. Measuring therapeutic response in chronic graft-versus-host disease. National Institutes of Health consensus development project on criteria for clinical trials in chronic graft-versus-host disease: IV. The 2014 Response Criteria Working Group report. Biol Blood Marrow Transplant. 2015 Jun;21(6):984-99. Doi: 10.1016/j.bbmt.2015.02.025.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.09	Other complications of bone marrow transplant

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC