Neighborhood Health Plan OF RHODE ISLAND™
910 Douglas Pike, Smithfield, RI 02917 : 1-800-963-1001 : nhpri.org

Niktimvo (axatilimab-csfr) (Intravenous)

Effective Date: 06/01/2025
Review Date: 05/14/2025
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

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

II. Dosing Limits

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

- 35 mg or 350 units every 2 weeks

III. Summary of Evidence:

Niktimvo (axatilimab-csfr) 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. The efficacy of Niktimvo was demonstrated in the Phase II AGAVE-201 trial, an open-label, multicenter study enrolling patients with recurrent or refractory cGVHD who had received at least two prior lines of systemic therapy. The primary endpoint was the overall response rate (ORR) through Cycle 7 Day 1, where overall response included complete response or partial response according to the 2014 NIH Consensus Development Project on Response Criteria. Overall response rates observed across different dosing cohorts. Notably, patients with fibrotic manifestations of cGVHD showed meaningful responses, highlighting Niktimvo's potential in addressing this challenging aspect of the disease. The trial met its primary endpoint, with significant overall response rates observed across different dosing cohorts. The most common adverse reactions reported with Niktimvo include laboratory abnormalities (elevations in AST, ALT, GGT, lipase, amylase, calcium, CPK, and ALP; decreases in phosphate and hemoglobin).

IV. Initial Approval Criteria

Coverage for is provided for treatment of the following conditions:

- Patient is at least 6 years of age; AND
- Patient weighs at least 40 kg; AND

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

- Patient has documentation of recurrent or refractory disease; AND
- The medication is prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients
- Used as a single agent or in conjunction with systemic steroids, calcineurin inhibitors (e.g., cyclosporine, 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 (e.g. methylprednisolone, cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil, imatinib); **AND**
- Niktimvo will not be prescribed in combination with Imbruvica, Jakafi or Rezurock; **OR**
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

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

V. Renewal Criteria

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section IV; 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.)

VI. Dosage/Administration

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.

VII. Billing Code/Availability information

HCPCS Code:

- J9038 – injection, axatilimab-csfr, 0.1mg

NDC:

- Niktimvo 9 mg/0.18 mL solution in a single-dose vial: 50881-0034-xx
- Niktimvo 22 mg/0.44 mL solution in a single-dose vial: 50881-0023-xx

VIII. References

1. Niktimvo [package insert]. Wilmington, DE; Incyte, Inc. January 2025. Accessed March 2025.
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 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 2024.
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)
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

Policy Rationale:

Niktimvo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Niktimvo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.