Niktimvo™ (axatilimab-csfr)
(Intravenous)

Document Number: IC-0767

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

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

- 360 billable units every 2 weeks

III. Initial Approval Criteria [1]

Prior authorization validity 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 [1-5]

- 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 mammalian target of rapamycin (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; **AND**
- For patients 12 years and older, patient has had an inadequate response to an adequate trial of, or contraindication or intolerance to belumosudil

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

IV. Renewal Criteria [1,6]

Prior authorization validity 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., National Institutes of Health (NIH) Skin Score, Upper Gastrointestinal (GI) Response Score, NIH Lung Symptom Score, etc.)
  - Patient-reported symptoms (e.g., Lee Symptom Scale, etc.)

V. Dosage/Administration [1]

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:

- J9038 – Injection, axatilimab-csfr, 0.1 mg; 1 billable unit = 0.1 mg

NDC(s):

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

VII. References

1. Niktimvo [package insert]. Wilmington, DE; Incyte Corporation. January 2025. Accessed October 2025.
2. Rezurock [package insert]. Warrendale, PA; Kadmon Pharm., Inc. April 2023. Accessed October 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for axatilimab. National Comprehensive Cancer Network, 2025. 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 October 2025.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Hematopoietic Cell Transplantation (HCT) Version 3.2025. 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 October 2025.

5. 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.
6. 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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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		
Jurisdictio	**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