Generic Name: Axatilimab-csfr

Therapeutic Class or Brand Name: Niktimvo™

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/8/2025

Date Last Reviewed / Revised: 9/8/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of chronic graft-versus-host disease (cGVHD) and all the following criteria are met:

   A. Documented treatment failure of at least two lines of systemic therapy (eg, corticosteroids, tacrolimus, mycophenolate mofetil, etc.).

   B. Minimum weight requirement: 40 kg.

II. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.

III. Request is for a medication with the appropriate FDA labeling and dosage, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Adults and children weighing less than 40 kg.
- Concurrent use of Jakafi, Imbruvica, or Rezurock.

OTHER CRITERIA

- Medical benefit for IV infusion.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities to provide 0.3 mg/kg (max 35 mg) every 2 weeks.

APPROVAL LENGTH

- **Authorization:** 12 months.
- **Re-Authorization Length and Renewal Criteria:** 12 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Niktimvo. Prescribing information. Incyte; 2025. Accessed August 17, 2025. https://www.incytepicentral.com/sites/g/files/hssmmz4016/files/2025-01/niktimvo-prescribing-information2025.pdf#page=1
2. Wolff D, Cutler C, Lee SJ, et al. Axatilimab in Recurrent or Refractory Chronic Graft-versus-Host Disease. New England Journal of Medicine. 2024;391(11):1002-1014. doi:10.1056/nejmoa2401537
3. NCCN Clinical Practice Guidelines in Oncology. Hematopoietic Cell Transplantation. Version 2.2025. Updated June 3, 2025. Accessed August 17, 2025. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf