Clinical Policy: Axatilimab-csfr (Niktimvo)

Reference Number: PA.CP.PHAR.691
Effective Date: 11/2024
Last Review Date: 10/2024

Description
Axatilimab-csfr (Niktimvo™) is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody.

FDA Approved Indication(s)
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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Niktimvo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Graft-Versus-Host Disease (must meet all)**:**

1. Diagnosis of cGVHD post hematopoietic cell transplantation;
2. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist;
3. Weight ≥ 40 kg;
4. Failure of a systemic corticosteroid (see Appendix B for examples) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a systemic immunosuppressant* (see Appendix B for examples) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; *Prior authorization may be required
6. Niktimvo is not prescribed concurrently with Jakafi®, Imbruvica®, or Rezurock®;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 0.3 mg/kg (up to maximum of 35 mg) every 2 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Graft-Versus-Host Disease (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Niktimvo is not prescribed concurrently with Jakafi, Imbruvica, or Rezurock;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 0.3 mg/kg (up to maximum of 35 mg) every 2 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
cGVHD: chronic graft-versus-host disease
CSF-1R: colony stimulating factor-1 receptor
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Systemic corticosteroids (e.g., methylprednisolone, prednisone)	Varies	Varies
Jakafi (ruxolitinib)	10 mg PO BID	20 mg/day*
Imbruvica (ibrutinib)	420 mg PO QD	420 mg/day
Rezurock (belumosudil)	200 mg PO QD	200 mg/day
Campath® (alemtuzumab) †	10 mg SC QD for 3 days or 3 mg IV TIW, then 10 mg IV weekly	See regimen

tacrolimus (Prograf®)†	0.15 mg/kg PO BID	Based on serum concentrations
cyclosporine (Gengraf®, Neoral®, Sandimmune®)†	6 mg/kg PO BID	Based on serum concentrations
Enbrel® (etanercept)†	0.4 mg/kg SC TIW	50 mg/week
imatinib (Gleevec®)†	100 mg PO QD	400 mg/day
sirolimus (Rapamune®)†	0.25 to 0.5 mg PO QD	40 mg/day*
mycophenolate mofetil (Cellcept®)†	240 mg PO QID or 1 g PO BID	2 g/day*
Nipent (pentostatin)†	4 mg/m^2 IV every 2 weeks	4 mg/m^2 /2 weeks*
rituximab (Riabni®, Rituxan®, Ruxience®, Truxima®)†	375 mg/m^2 IV weekly	1,000 mg/week*

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Maximum dose of the drug, not indication specific*
†Off-label

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
cGVHD	0.3 mg/kg (up to a maximum of 35 mg) IV infusion every 2 weeks	35 mg/2 weeks

VI. Product Availability

Single-dose vial: 50 mg/mL

VII. References

1. Niktimvo Prescribing Information. Wilmington, DE: Incyte Corporation; August 2024. Available at: www.niktimvohcp.com. Accessed September 3, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2024. Available at: http://www.clinicalkey.com/pharmacology/. Accessed September 3, 2024.
3. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT) 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed September 3, 2024.
4. ClinicalTrials.gov. NCT04710576. A study of axatilimab at 3 different doses in participants with chronic graft versus host disease (cGVHD) (AGAVE-201). Available at: www.clinicaltrials.gov. Accessed September 4, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date
Policy created	10/2024