Clinical Policy: Axatilimab-csfr (Niktimvo)

Reference Number: LA.PHAR.691
Effective Date:
Last Review Date: 11.27.24
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

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 Louisiana Healthcare Connections® 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. Age ≥ 6 years;
4. Weight ≥ 40 kg;
5. 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;
6. 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*
7. Niktimvo is not prescribed concurrently with Jakafi®, Imbruvica®, or Rezurock®;
8. 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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Graft-Versus-Host Disease (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Niktimvo for a covered indication and has received this medication for at least 30 days;
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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

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 – LA.PMN.53 for Medicaid or evidence of coverage documents.

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 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	LDH Approval Date
Converted corporate to local policy.	11.27.24	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC-level administrative policies and procedures.

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