Clinical Policy: Axatilimab-csfr (Niktimvo)

Reference Number: CP.PHAR.691
Effective Date: 12.01.24
Last Review Date: 11.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

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 health plans affiliated with Centene Corporation® 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/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; 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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Graft-Versus-Host Disease (must meet all)**:**
1. Currently receiving medication via Centene 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/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; 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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 not be a formulary agent for all relevant lines of business 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*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 vials: 9 mg/0.18 mL, 22 mg/0.44 mL, 50 mg/mL

VII. References

1. Niktimvo Prescribing Information. Wilmington, DE: Incyte Corporation; January 2025. Available at: www.niktimvohcp.com. Accessed January 23, 2025.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2025. 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 January 23, 2025.
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
J9038	Injection, axatilimab-csfr, 0.1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.03.24	11.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: added new dosage strengths of 9 mg/0.18 mL and 22 mg/0.44 mL. HCPCS code added [J9038], removed codes [J3590, C9399].	02.13.25	

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.