Drug Coverage Policy

Effective Date.....08/01/2025
Coverage Policy Number.....IP0722
Policy Title.....Niktimvo

Graft-Versus-Host Disease - Niktimvo

- Niktimvo™ (axatilimab-csfr intravenous infusion - Incyte/Syndax)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview
Niktimvo, a colony stimulating factor-1 receptor-blocking antibody, is indicated for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

Guidelines
Niktimvo has been addressed in the National Comprehensive Cancer Network Hematopoietic Cell Transplantation guidelines (version 1.2025 – February 28, 2025). Options for first-line therapy for chronic GVHD including restarting, continuing, or escalating the original immunosuppressive agent(s) and/or administering systemic corticosteroids (0.5 to 1 mg/kg day of methylprednisolone or prednisone dose equivalent). Among the agents FDA-approved for use in chronic GVHD, Jakafi® (ruxolitinib tablets) is the only agent given a category 1 recommendation for chronic GVHD. Niktimvo, Rezurock® (belumosudil tablets), and Imbruvica® (ibrutinib tablets, capsules, and oral suspension) each have a category 2A recommendation. The guidelines cite that each of these FDA-approved agents should be used following failure of one or two lines of systemic therapy (depending on the agent). Other medication alternatives include Orencia® (abatacept intravenous [IV] infusion and subcutaneous [SC] injection), Lemtrada® (alemtuzumab IV infusion), calcineurin inhibitors (e.g., tacrolimus, cyclosporine), Enbrel® (etanercept SC injection), extracorporeal photopheresis, hydroxychloroquine, imatinib, Proleukin® (aldesleukin IV infusion and SC injection), low-dose methotrexate, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, pentostatin, and rituximab.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Niktimvo. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Niktimvo is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Graft-Versus-Host Disease.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy: Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 40 kg; AND
     - **ii.** Patient has chronic graft-versus-host disease; AND
     - **iii.** Patient has tried at least two systemic medications for chronic graft-versus-host disease.
       Note: Examples of systemic therapy include Jakafi (ruxolitinib tablets), Rezurock (belumosudil tablets), Imbruvica (ibrutinib tablets, capsules, and oral suspension), imatinib, hydroxychloroquine, methotrexate, rituximab, pentostatin, interleukin-2 (e.g., Proleukin [aldesleukin intravenous infusion]), methylprednisolone, cyclosporine, tacrolimus, sirolimus, an etanercept product, and mycophenolate mofetil.
   - **B)** Patient Currently Receiving Niktimvo: Approve if according to the prescriber, the patient demonstrates a beneficial clinical response.

Note: Examples of a beneficial response include a reduction in corticosteroid dose, disease stabilization, and/or symptomatic improvement.

Dosing. Approve 0.3 mg/kg (up to a maximum dose of 35 mg) given as an intravenous infusion once every 2 weeks.

Conditions Not Covered

Niktimvo for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J9038	Injection, axatilimab-csfr, 0.1 mg

References

1. Niktimvo™ intravenous infusion [prescribing information]. Wilmington, DE and Waltham, MA: Incyte/Syndax; January 2025.
2. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 1.2025 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	05/15/2025
Annual Revision	Graft-Versus-Host Disease was added to the header. **Graft-Versus-Host Disease**, For initial therapy, for the requirement that a patient tried two systemic treatments, the descriptor "conventional" was removed and the word "therapies" was changed to "medications." Also, an etanercept product was listed in the Note that cites examples of systemic therapy for chronic graft-versus-host disease. Removed "for 1 year" under both Initial Therapy and Patient currently receiving Niktimvo sections.	8/1/2025

The policy effective date is in force until updated or retired.