CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Niktimvo (axatilimab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Niktimvo is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody 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.
GVHD is a complication following allogeneic hematopoietic stem cell transplant (HSCT). It occurs when immune cells transplanted from a non-identical donor (graft) recognize the transplant recipient (host) as foreign, initiating an immune response. Chronic GVHD typically occurs more than 100 days posttransplant and involves multiple organ systems. Steroids are the mainstay of treatment but many patients require 2 or more lines of therapy.
Niktimvo is a first-in-class drug to target CSF-1R expressed on monocytes and macrophages. Blocking CSF-1R reduces the levels of these circulating proinflammatory and profibrotic monocytes and monocyte-derived macrophages and inhibits the activity of pathogenic macrophages in tissues.

Niktimvo (axatilimab) will be considered for coverage when the following criteria are met:

Chronic graft-versus-host disease (cGVHD)

For **initial** authorization:
1. Member weighs at least 40 kg; AND
2. Medication must be prescribed by or in consultation with a transplant or hematology/oncology specialist; AND
3. Member has a documented diagnosis of cGVHD following allogeneic hematopoietic stem cell transplantation (HSCT); AND
4. Member has failed at least 2 prior lines of systemic therapy, i.e., systemic corticosteroid and another systemic treatment (calcineurin inhibitor, Jakafi, mycophenolate mofetil, sirolimus, methotrexate, Imbruvica).
5. **Dosage allowed/Quantity limit:** IV infusion; 0.3 mg/kg over 30 minutes every 2 weeks until progression or unacceptable toxicity. Max dose 35 mg.
   QL: 2 vials (2 mL) per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement of signs and symptoms of disease in at least 1 organ/site, without progression in any other organ/site.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Niktimvo (axatilimab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/19/2024	New policy for Niktimvo created.

References:

1. Niktimvo. [prescribing information]. Incyte Corporation; 2024.
2. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT). Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed September 20, 2024.

Effective date: 02/01/2026
Revised date: 09/19/2024