

Medical Drug Clinical Criteria

Subject: Niktimvo (axatilma-b-csfr)
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Overview

This document addresses the use of Niktimvo (axatilma-b-csfr) is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody primarily used to treat chronic graft-versus-host disease after failure of prior treatments.

Niktimvo (axatilma-b-csfr) is FDA 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.

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Niktimvo for chronic graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following failure (steroid-refractory disease) to at least two prior lines of systemic therapy in patients ≥40 kg.

Definitions and Measures

Adenocarcinoma: Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.

Adjuvant therapy: Treatment given after the primary treatment to increase the chances of a cure; may include chemotherapy, radiation, hormone or biological therapy.

Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

Complete Response (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.

Disease Progression: Cancer that continues to grow or spread.

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Hematopoietic stem cells: Primitive cells capable of replication and formation into mature blood cells in order to repopulate the bone marrow.

Line of Therapy:

- **First-line therapy:** The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.

- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Maintenance therapy: Designed to maintain a condition to prevent a relapse.

Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Primary refractory disease: Cancer that does not respond at the beginning of treatment; may also be called resistant disease.

Progression free survival (PFS): The length of time during and after treatment that an individual lives but does not get worse (usually measured by the size of a tumor or amount of cancer in the body).

Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Stable disease: Cancer that is not decreasing or increasing in extent or severity.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Niktimvo (axatilimab-csfr)

Requests for Niktimvo (axatilimab-csfr) may be approved if the following criteria are met (Label, NCCN 2A):

- I. Individual has a diagnosis of chronic graft-versus-host disease (cGVHD); **AND**
- II. Individual is using after failure of at least two prior lines of systemic therapy; **AND**
- III. Individual weighs at least ≥ 40 kg;

Requests for Niktimvo (axatilimab-csfr) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9038	Injection, axatilimab-csfr, 0.1 mg [Niktimvo]
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ICD-10 Diagnosis

D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
T86.09	Other complications of bone marrow transplant

Document History

New: 09/09/2024

Document History:

- 03/04/2025 – Coding Update: Removed HCPCS NOC J3590, C9399 and all diagnosis pend for Niktimvo. Added HCPCS J9038 effective 4/1/25. Added ICD-10-CM D89.811, D89.812, and T86.09.
- 09/09/2024 – Select Review: New prior authorization policy for Niktimvo. Coding Reviewed: Add HCPCS J3590 and C9399 for Niktimvo and all diagnosis pend for NOC codes.

References

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on August 30, 2024.
 - a. Hematopoietic Cell Transplantation. V1.2024. Revised April 26, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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