Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Axatilmab-csfr (Niktimvo®)	MP-RX-FP-159-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Axatilmab-csfr (Niktimvo®), a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved by the Food and Drug Administration (FDA) 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.

Background Information

Niktimvo (axatilmab-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.

According to the product label, Niktimvo is indicated for patients weighing at least 40 kg, administered at a dose of 0.3 mg/kg, up to a maximum of 35 mg. It is delivered as an intravenous infusion over 30 minutes every two weeks and continues until disease progression or the onset of unacceptable toxicity.

The product label also list as warnings Infusion-related reactions (reported in 18% of patients in the pivotal clinical trial AGAVE-201), and a potential risk of embryo-fetal toxicity based on its mechanism of action. It may cause harm to the fetus if administered to pregnant women. Females of reproductive potential should be informed of this risk and advised to use effective contraception during treatment and for 30 days after the final dose.

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.

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- 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.

Approved Indications

Axatilmab-csfr (Niktimvo®) Is approved by the FDA 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.

Other Uses

None

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3590	Unclassified biologics (Niktimvo)
C9399	Unclassified drugs or biologicals (Niktimvo)

ICD-10	Description
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.09	Other complications of bone marrow transplant

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Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Axatilmab-csfr (Niktimvo®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Requests for Niktimvo (axatilmab-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;

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Axatilmab-csfr (Niktimvo®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
    A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
    B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Axatilmab-csfr (Niktimvo®) 50 mg/mL solution (single-dose vial)	0.3 mg/kg, up to a maximum dose of 35 mg, as an intravenous infusion over 30 minutes every 2 weeks until progression or unacceptable toxicity.
Exceptions	
None	

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 30, 2024.
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 polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption	12/9/2024	12/17/2024

Revised: 08/30/2024