AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Niktimvo™ (axatilimab-csfr) **(J9038) MEDICAL**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 9 mg/0.18 mL single dose vial: 2 vials every 2 weeks
- 22 mg/0.44 mL single dose vial: 1 vial every 2 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

- 35 mg once every 2 weeks
- 9 mg/0.18 mL single dose vial: 1 vial = 90 billable units; 2 vials = 180 billable units
- 22 mg/0.44 mL single dose vial: 1 vial = 220 billable units

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is at least 6 years of age or older
- ❑ Member weighs at least 40 kg
- ❑ Provider is an oncologist/hematologist, or in consultation with a transplant specialty clinic
- ❑ Requested medication is being used for disease related to allogeneic hematopoietic stem cell transplantation
- ❑ Member does **NOT** have histologic relapse of underlying cancer or post-transplant lymphoproliferative disease
- ❑ Member does **NOT** have acute or chronic pancreatitis
- ❑ Member does **NOT** have a history of myositis
- ❑ Member has failed **two or more** previous lines of systemic therapy for the treatment of cGVHD (e.g., corticosteroids, immunosuppressants) (verified by pharmacy paid claims)
- ❑ Requested therapy will be used as a single agent or in combination with stable doses of systemic therapies for cGVHD which must include, but are not limited to, corticosteroids, calcineurin inhibitors, or mTOR inhibitors (e.g., sirolimus, everolimus, etc.) **(verified by pharmacy paid claims)**
- ❑ Provider has submitted progress notes and/or clinical assessment documenting the symptomology and staging/severity confirming refractory or recurrent active cGVHD (i.e. NIH Global Severity Score, NIH Organ-specific Score)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to all initial authorization criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe infusion related reactions, periorbital edema)
- ❑ A response to therapy noted by observation of stable disease or mild progression recorded in one or more of the following:
  - ❑ Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.)
  - ❑ Patient-reported symptoms (e.g., modified 28-item Lee Symptom Scale, etc.)

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****