RX.PA.104.MPC Niktimvo™ (axatilimab-csfr) Injection

The purpose of this policy is to define the prior authorization process for Niktimvo (axatilimab-csfr) IV.

PROCEDURE

A. <u>Initial Authorization Criteria:</u>

All requests for Niktimvo™ (axatilimab-csfr) must meet the following criteria:

- Patient is an allogeneic hematopoietic stem cell transplant (HSCT) recipient and has a documented diagnosis of chronic graft versus host disease (cGVHD)
- Patient is at least 2 years of age or older
- Patient's weight is at least 40kg
- Patient has documentation of a trial and failure, intolerance to, or contraindication to a systemic corticosteroid at maximally tolerated dose
- Patient has documentation of refractory or recurrent active cGVHD despite a trial and failure of two prior systemic therapies (e.g. tacrolimus, cyclosporine, mycophenolate, methotrexate, sirolimus, etc.) (Note: Trial and failure of systemic therapies does not include corticosteroids).
    - Refractory/recurrent disease is defined as at least one of the following:
        - The development of one or more new sites of disease while being treated for cGVHD
        - Progression of existing sites of disease despite at least one month of treatment for cGVHD
        - Patient has not achieved a response after three months of prior therapy for cGVHD and for whom the treating physician believes a new systemic therapy is required
        - Active, symptomatic disease after an initial response to prior therapy
- Provider attestation of discussion with patients (males and females) of child bearing age of effective contraception use
- Must be prescribed by or in consultation with an oncologist, hematologist, or transplant specialist
- Must have documentation of trial and failure, intolerance to, or contraindication to Jakafi (ruxolitinib) and Imbruvica (Ibrutinib)
- Must not be used concurrently with Jakafi (ruxolitinib), Imbruvica (ibrutinib), or Rezurock (belumosudil)

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

Reauthorization Criteria:

Patient is currently receiving Niktimvo™ (axatilimab-csfr). Must meet the following criteria (A or B):

A. MPC Renewal

- Patient has a documented clinically significant response, as determined by the provider
- Patient does not have any evidence of unacceptable toxicity or disease progression
- Must be prescribed by or in consultation with an oncologist, hematologist, or transplant specialist
- Must not be used concurrently with Jakafi (ruxolitinib), Imbruvica (ibrutinib), or Rezurock (belumosudil)

OR

B. Renewal from Previous Insurer:

- Patients who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria); AND
- Patients have a documented clinically significant response, as determined by the provider

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

Codes:

Code	Description
J9038	Injection, axatilimab-csfr, 0.1 mg

REFERENCES

1. Niktimvo [package insert]. Wilmington,DE; Incyte, Inc.; January 2025.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*03/2025*