axatilimab-csfr (Niktimvo)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Colony stimulating factor-1 receptor (CSF-1R)-blocking antibody
HCPCS:
J9038:Injection, axatilimab-csfr, 0.1 mg
How Supplied:
9 mg/0.18 mL solution in a single-dose vial
22 mg/0.44 mL solution in a single-dose vial
50 mg/mL solution in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Chronic Graft-Versus-Host Disease (GVHD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Chronic Graft-Versus-Host Disease (GVHD)
Meets medical necessity if all the following are met:
1. Inadequate response to at least two prior systemic therapies (i.e., systemic corticosteroids, immunosuppressants)
2. Patient weighs at least 40 kg

Covered Doses:
Up to 0.3 mg/kg (maximum of 35 mg) given intravenously every 2 weeks

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
D89.811, D89.812, D89.813, T86.09

References

1. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (Version 2.2025). Available at www.nccn.org.
2. Niktimvo (axatilimab-csfr) Prescribing Information. Incyte Corporation, Wilmington, DE: 1/2025.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee