



Niktimvo
Adagen (axatilimab-csfr) J9038
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

- Chronic Graft-Versus-Host Disease (cGVHD) – Refractory**
- Patient is 18 years or older
 - Confirmed diagnosis of chronic graft-versus-host disease following allogeneic hematopoietic stem cell transplant
 - Patient has received at least two prior lines of systemic therapy for cGVHD
 - Patient has refractory disease (inadequate response or intolerance) to prior therapies
 - ECOG performance status 0-2
 - Prescribed by or in consultation with transplant specialist or hematologist/oncologist
 - No active uncontrolled infection

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Patient had an **adequate response** or **significant improvement** while on this medication.

Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Niktimvo Prior Authorization

Drug Name(s):

NIKTIMVO

AXATILIMAB-CSFR

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan, in accordance with Label.
 - Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Transplant Specialist or Hematologist/Oncologist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Niktimvo

- Graft-versus-host disease, chronic, After failure of at least 2 prior lines of systemic therapy

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexolutions.com/micromedex2/librarian/CS/1714B9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/294F05/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=934486&contentSetId=100&title=Axatilimab-csfr&servicesTitle=Axatilimab-csfr&brandName=Niktimvo&UserMdxSearchTerm=niktimvo#