HIGHMARK WHOLECARE

Updated: 06/2025
PARP Approved: 07/2025

Prior Authorization Criteria

Joenja (leniolisib)

All requests for Joenja (leniolisib) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of **activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)** and the following criteria is met:

- Must be prescribed by or in consultation with a specialist (e.g., hematologist, genetic specialist)
- Must have genetic testing confirming the PI3Kδ mutation with a documented variant in either PIK3CD or PIK3R1
- Must have clinical findings and manifestations compatible with APDS (e.g. history of repeated oto-sino-pulmonary infections, organ dysfunction)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- **Duration of Approval:** 12 months
- **Reauthorization Criteria:**
    - Documentation of improvement
- **Reathorization Duration:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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JOENJA (LENIOLISIB)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Has a PI3Kδ mutation with a variant in either PIK3CD or PIK3R1 been confirmed by genetic testing? ☐ Yes ☐ No

Are clinical findings and manifestations compatible with APDS (e.g. repeated infections, organ dysfunction)? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced an improvement with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date