Updated: 06/2025
DMMA Approved: 06/2025

Request for Prior Authorization for Joenja (leniolisib)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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

Prior Authorization Criteria:

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)
- Must have a trial and failure or contraindication to traditional treatment for primary immunodeficiency (e.g., IVIG).
- 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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

HIGHMARK HEALTH OPTIONS

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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 Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8:00 am to 7:00 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

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

Has traditional treatment for primary immunodeficiency been tried and failed (e.g. IVIG)? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date