Kaiser Permanente Health Plan of Mid-Atlantic States, Inc.
Joenja (leniolisib) Prior Authorization (PA)
Pharmacy Benefits Prior Authorization Help Desk
Length of Authorizations: Initial- 12 months; Continuation- 12 months

Instructions:

This form is used by Kaiser Permanente and/or participating providers for coverage of **Joenja (leniolisib).** Please complete all sections, incomplete forms will delay processing. Fax this form back to Kaiser Permanente within 24 hours (fax: 1-866-331-2104). If you have any questions or concerns, please call 1-866-331-2103. **Requests will not be considered unless all sections are complete.**

KP-MAS Formulary can be found at: Pharmacy | Community Provider Portal | Kaiser Permanente

1 – Patient Information

Patient Name: _____ Kaiser Medical ID#: _____ Date of Birth: _____

2 – Prescriber Information

Prescriber Name: _____ Specialty: _____ NPI: _____

Prescriber Address: _____

Prescriber Phone #: _____Prescriber Fax #: _____

Do you have an approved provider referral number from Kaiser Permanente?
□ Yes – please provide your provider referral number here: _____

3 – Pharmacy Information

Pharmacy Name: _____ Pharmacy NPI: _____

Pharmacy Phone #_____ Pharmacy Fax #: _____

4 – Drug Therapy Requested

Drug 1: Name/Strength/Formulation: _____
Sig: _____

Drug 2: Name/Strength/Formulation: _____
Sig: _____

5– Diagnosis/Clinical Criteria

1. Is this request for initial or continuing therapy?
   □ Initial therapy □ Continuing therapy, state start date: _____

2. Indicate the patient's diagnosis for the requested medication: _____

Clinical Criteria:

1. Is the patient 12 years of age or older, and weighing ≥45 kg?
   □ No □ Yes

2. Does the patient have a confirmed diagnosis of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS), as demonstrated by the presence of an APDS-assocaited genetic PI3Kδ mutation with a documented variant in either *PIK3CD* or *PIK3R1*?
   □ No □ Yes

3. Does the patient have nodal and/or extranodal lymphoproliferation, with the presence of at least 1 measurable nodal lesion, as measured on computed tomography (CT) or magnetic resonance imaging (MRI)?
   □ No □ Yes

4. Does the patient have clinical findings and manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, organ dysfunction, e.g., lung, liver)?
   □ No □ Yes

5. Has pregnancy status been confirmed in individuals of reproductive potential prior to initiating therapy, and will highly effective methods of contraception be used during treatment?
   □ No □ Yes

6. Will the patient avoid concomitant therapy with ALL of the following?
   a. Coadministration with strong and moderate CYP3A4 inducers (e.g., rifampin, bosentan, efavirenz, etravirine, St. John's Wort)
   b. Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin)

   □ No □ Yes

7. Will the patient avoid concurrent immunosuppressive therapy (e.g., mammalian target of rapamycin (mTOR) inhibitors, B-cell depleters, glucorticoids (doses >25 mg/day of prednisone equivalent), cyclophosphamide, mycophenolate)?
   □ No □ Yes

For continuation of therapy, please respond to <u>additional questions</u> below:

1. Does the patient continue to meet initial review criteria?
   □ No □ Yes

2. Has the patient had disease response with treatment, as defined as stabilization of, or improvement of disease signs and symptoms?
   □ No □ Yes

3. Has the patient been assessed for toxicity?
   □ No □ Yes

6 – Prescriber Sign-Off

Additional Information –

1. **Please submit chart notes/medical records for the patient that are applicable to this request.**
2. **If member has not tried preferred agent(s) please provide rationale/explanation and any additional supporting information that should be taken into consideration for the requested medication:**

_____

_____

_____

I certify that the information provided is accurate. Supporting documentation is available for State audits.

Prescriber Signature:	**Date:**