Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 25, 2023 January 24, 2024, March 25, 2024, April 9, 2024

Joenja® (leniolisib)

LENGTH OF AUTHORIZATION: 1 year

REVIEW CRITERIA:

- Patient must be ≥ 12 years of age and have a weight ≥ 45 kg; **AND**
- Patient has a diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS) with a confirmed PI3Kδ genetic mutation and documented variant in either the PIK3CD or PIK3R1 gene; **AND**
- Patient has at least one clinical finding or manifestation consistent with APDS (e.g., history of repeated oto-sino-pulmonary infections, organ dysfunction [e.g., lung, liver, etc.]); **OR**
- Diagnostic imaging test (e.g., Computed tomography [CT] or magnetic resonance imaging [MRI]) confirming the presence of at least one measurable nodal lesion; **AND**
- Patient does not have moderate or severe liver impairment; **AND**
- For female patients of reproductive potential: Attestation that the patient is not pregnant, and highly effective contraception methods will be used during treatment and for 1 week after the last dose; **AND**
- Patient is not on concurrent immunosuppressive therapy (e.g., everolimus, sirolimus, cyclophosphamide, mycophenolate, B-cell depleters, glucocorticoids [doses > 25 mg/day of Prednisone equivalent], etc.); **AND**
- Must be prescribed by or in consultation with an immunologist or related specialist.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Patient must have disease response with treatment as defined by stabilization of or improvement of disease signs and symptoms (e.g., decrease in the frequency and/or severity of infections, decreased lymphadenopathy, increased percentage of naïve B cells); **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., severe neutropenia: absolute neutrophil count [ANC] < 500 cells/µL); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 70 mg tablets.