

leniolisib (JOENJA)

Diagnoses Considered for Coverage:

- Activated phosphoinositide 3-kinase delta (PI3K δ) syndrome (APDS)

Coverage Criteria:

1. **For member new to Blue Shield (within the past 6 months), approve if:**
 - Started and stabilized on the medication prior to joining Blue Shield, **and**
 - Being used for a covered diagnosis, **and**
 - Dose does not exceed FDA label maximum.
2. **For activated phosphoinositide 3-kinase delta (PI3K δ) syndrome (APDS), approve if:**
 - Patient is at least 12 years old, **and**
 - Diagnosis confirmed by the presence of APDS associated genetic PIK3CD/PIK3R1 mutation, **and**
 - Not being used in combination with immunosuppressive therapy (i.e., rituximab, rapamycin, or tacrolimus), **and**
 - Dose does not exceed 140 mg per day.

Coverage Duration: one year

References:

1. Joenja. Prescribing information. Pharming Technologies: 2023.

Effective Date: 5/31/2023