

JOENJA (leniolisib)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

Activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)

AND ALL of the following:

- 1. Confirmed APDS-associated genetic PI3Kδ mutation with a documented variant in either PIK3CD or PIK3R1
- 2. Patient weight \geq 45 kg
- 3. Female patients of reproductive potential **only**: Patient has had a negative pregnancy test **AND** prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose

Prior - Approval Limits

Quantity

Strength	Quantity Limit
70 mg	180 tablets per 90 days

Duration 12 months

Prior – Approval Renewal Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

Activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)

AND ALL of the following:

 Patient has had a clinical benefit from therapy (e.g., increased B cells and T cells)



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2. Female patients of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose

Prior - Approval Renewal Limits

Same as above