



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Joenja (leniolisib) Page: 1 of 2

Effective Date: 12/26/2023 Last Review Date: 10/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Joenja under the patient's prescription drug benefit.

### Description:

Joenja is indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS) in adults and pediatric patients 12 years of age and older

All other indications are considered experimental/investigational and not medically necessary.

### Applicable Drug List:

Joenja (leniolisib)

### Policy/Guideline:

#### Criteria for Initial Approval:

#### Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Testing or analysis confirming a mutation of either *PIK3CD* or *PIK3R1* gene.
- Medical record documentation confirming the member demonstrates clinical manifestations of the disease (e.g., history of repeated oto-sino-pulmonary infections, lymphoproliferation, autoimmunity [e.g., cytopenia], enteropathy, organ dysfunction [e.g., lung, liver]).

#### Activated phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS)

Authorization may be granted when all the following criteria are met:

- Joenja must be prescribed by or in consultation with an immunologist or a physician who specializes in the treatment of APDS.
- Member's diagnosis is confirmed by detection of mutation of either *PIK3CD* or *PIK3R1* gene.
- Member has clinical manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, lymphoproliferation, autoimmunity [e.g., cytopenia], enteropathy, organ dysfunction [e.g., lung, liver]).
- Member is 12 years of age and older weighing greater than or equal to 45 kg

#### Criteria for Continuation of Therapy:



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### Activated phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS)

Authorization may be granted for continued treatment for all members (including new members), who are currently receiving the requested medication, when all the following criteria are met:

- A. Joenja must be prescribed by or in consultation with an immunologist or a physician who specializes in the treatment of APDS.
- B. Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement.

### Approval Duration and Quantity Restrictions:

**Initial:** 6 months

**Renewal:** 12 months

**Quantity Level Limit:** 60 tablets per 30 days

### References:

1. Joenja [package insert]. Warren, NJ: Pharming Technologies B.V.; March 2023.
2. Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3K $\delta$  inhibitor leniolisib for activated PI3K $\delta$  syndrome. *Blood*. 2023;141(9):971-983. doi:10.1182/blood.2022018546.