



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 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 δ) 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 δ) 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 δ) 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 δ inhibitor leniolisib for activated PI3K δ syndrome. *Blood*. 2023;141(9):971-983. doi:10.1182/blood.2022018546.