		<b>AETNA BETTER HEALTH®</b> Coverage Policy/Guideline	
Name:	Joenja (leniolisib)	Page:	1 of 2
Effective Date:	1/13/2025	Last Review Date:	11/25/2024
Applies to:	<input checked="" type="checkbox"/> Illinois <input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> New Jersey <input checked="" type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Maryland <input checked="" type="checkbox"/> Virginia

### 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 (PI3Kδ) 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:

- A. Testing or analysis confirming a mutation of either *PIK3CD* or *PIK3R1* gene.
- B. 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 (PI3Kδ) syndrome (APDS)

Authorization may be granted 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's diagnosis is confirmed by detection of mutation of either *PIK3CD* or *PIK3R1* gene.
- C. 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]).
- D. Member is 12 years of age and older weighing greater than or equal to 45 kg

#### Criteria for Continuation of Therapy:

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

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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. Joenia 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. Joenia [package insert]. Warren, NJ: Pharming Healthcare Inc.; March 2023.
2. Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. Blood. 2023;141(9):971-983. doi:10.1182/blood.2022018546