AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Joenja (leniolisib)	Page:	1 of 2
Effective Date:	1/13/2026	Last Review Date:	12/2025

Applies to:	☒Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐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:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

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

Policy/Guideline:

Documentation

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

- Testing or analysis confirming a variation of either the 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]).

Prescriber Specialties

This medication must be prescribed by or in consultation with an immunologist or a physician who specializes in the treatment of APDS.

Coverage Criteria

Activated Phosphoinositide 3-kinase Delta (PI3Kδ) Syndrome (APDS)[1-3]

Authorization of 12 months may be granted for treatment of APDS when all of the following criteria are met:

- Member's diagnosis was confirmed by genetic test demonstrating variant in either the PIK3CD or PIK3R1 gene.
- Member has clinical manifestations of disease (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 or older and weighs greater than or equal to 45 kg.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in all members (including new members) who are currently receiving the requested medication and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Approval Duration and Quantity Restrictions:

Initial: 12 months
Renewal: 12 months

Quantity Level Limit: 60 tablets per 30 days

References:

1. Joenja [package insert]. Warren, NJ: Pharming Healthcare Inc.; May 2025.
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
3. Rao VK, Kulm E, Šedivá A, et al. Interim analysis: Open-label extension study of leniolisib for patients with APDS. J Allergy Clin Immunol. 2024;153(1):265-274. doi:10.1016/j.jaci.2023.09.032.