

Clinical Policy Title:	Joenja
Policy Number:	RxA.803
Drug(s) Applied:	Joenja
Original Policy Date:	10/19/2023
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Activated Phosphoinositide 3-Kinase Delta (PI3K δ) Syndrome (APDS) (must meet all):

1. Diagnosis of APDS;
2. Confirmation of genetic mutation in either PIK3CD (APDS1) or PIK3R1 (APDS2) gene;
3. Presence of clinical manifestations of APDS (e.g., nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction).

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. APDS

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. 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. Accessed March 24, 2025.
2. Rao VK, et al. Effective "activated PI3K δ syndrome"-targeted therapy with the PI3K δ inhibitor leniolisib. *Blood*. 2017;130(21):2307-2316. [doi:10.1182/blood-2017-08-801191][3]. Accessed March 24, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/19/2023	10/19/2023
Policy reviewed: Removed: 1. Age and weight restriction Added: 1. Continuation of treatment Changed: 1. Approval from 6 months to 12 months	3/15/2024	10/19/2023

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy was reviewed: 1. Removed prescriber criteria. 2. Updated approval duration verbiage. 3. Updated continuation of therapy language.	03/24/2025	04/10/2025
Policy reviewed.	12/11/2025	12/11/2025