

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2025 P 1413-3
Program	Prior Authorization/Notification
Medication	Joenja® (leniolisib)
P&T Approval Date	5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Joenja (leniolisib) is a kinase inhibitor indicated for the treatment activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.

2. Coverage Criteria^a:

A. Initial Authorization

- 1. **Joenja** will be approved based upon **both** of the following criteria:
 - a. Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)

-AND-

b. Patient is 12 years of age or older

Authorization will be issued for 12 months.

B. Reauthorization

- 1. **Joenja** will be approved based on the following criterion:
 - a. Documentation of positive clinical response to Joenja therapy

Authorization will be issued for 12 months.

^aState mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.



4. Reference:

1. Joenja [package insert]. Foster City, CA: Pharming Technologies, Inc.; March 2023.

Program	Prior Authorization/Notification - Joenja (leniolisib)
Change Control	
5/2023	New program
5/2024	Annual review. Updated initial authorization duration to 12 months.
5/2025	Annual review with no changes.