PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Joenja (leniolisib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Joenja, approved by the FDA in 2023, is a small molecule kinase inhibitor indicated for the treatment of activated phosphoinositide 3-
of age and older. It selectively targets signaling by inhibiting its hyperactive subunit.
APDS is also known as p110 -activating mutation causing senescent T cells, lymphadenopathy, and immunodeficiency (PASLI). It is an ultra-rare disease caused by variants in either of the genes encoding the (*PIK3CD* in APDS1 or *PIK3R1* in APDS2) which leads to .
This results in disrupted immune cell development and function. Clinical manifestations include infections, nonmalignant lymphoproliferation, autoimmunity (e.g., cytopenias), enteropathy, bronchiectasis, and increased risk of lymphoma.
In a Phase 3 study, Joenja met the coprimary endpoints of reducing lymphadenopathy and normalizing immune cell subsets. It is the first FDA-approved drug for APDS.

Joenja (leniolisib) will be considered for coverage when the following criteria are met:

Activated Phosphoinositide 3-Kinase D

For **initial** authorization:

1. M-7(e W* n 23>> BDC q 49.675 204.2 526.28 178.6 re W* n BT /F2 1 ET Q q 0.0000n BT3gsi E

DATE	ACTION/DESCRIPTION
04/24/2023	New policy for Joenja created.

References:

1. Joenja [prescribing information]. Pharming Technologies B.V.; 2023.
2. A, et al. A randomized, placebo-controlled phase 3 trial of *Blood*. 2023;141(9):971-983. doi:10.1182/blood.2022018546
3. Rao VK, Webster S, Dalm - inhibitor leniolisib. *Blood*. 2017;130(21):2307-2316. doi:10.1182/blood-2017-08-801191
4. *Front Immunol*. 2018;9:2043. Published 2018 Sep 7. doi:10.3389/fimmu.2018.02043
5. Singh A, Joshi V, Jindal AK, Mathew B, Rawat A. An updated review on activated PI3 kinase delta syndrome (APDS). *Genes Dis*. 2019;7(1):67-74. Published 2019 Oct 14. doi:10.1016/j.gendis.2019.09.015

Effective date: 10/01/2023
Revised date: 04/24/2023