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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 28, 2023
Subject:	Joenja	**Page:**	1 of 4

Last Review Date: March 8, 2024

Joenja

Description

Joenja (leniolisib)

Background
Joenja (leniolisib) inhibits phosphoinositide 3-kinase delta (PI3Kδ) by blocking the active binding site of PI3Kδ. Gain-of-function variants in the gene encoding the p110-delta catalytic subunit or loss of function variants in the gene encoding the p85-alpha regulatory subunit each cause hyperactivity of PI3Kδ. Joenja inhibits the signaling pathways that lead to increased production of PIP3, hyperactivity of the downstream mTOR/AKT pathway, and to the dysregulation of B and T cells (1).

Regulatory Status
FDA-approved indication: Joenja is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older (1).

Joenja has a warning regarding vaccinations. Live, attenuated vaccinations may be less effective if administered during Joenja treatment (1).

Joenja may cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of patients of reproductive potential prior to starting treatment. Females of reproductive potential should be advised to use highly effective methods of contraception during treatment and for 1 week after the last dose (1).

The safety and effectiveness of Joenja in pediatric patients less than 12 years of age have not been established (1).

Related policies
Vijoice

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Joenja may be considered **medically necessary** if the conditions indicated below are met.

Joenja may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

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

AND ALL of the following:

1. Confirmed APDS-associated genetic PI3Kδ mutation with a documented variant in either PIK3CD or PIK3R1
2. Patient weight ≥ 45 kg
3. Female patients of reproductive potential **only**: Patient has had a negative pregnancy test **AND** prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

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

AND ALL of the following:

1. Patient has had a clinical benefit from therapy (e.g., increased B cells and T cells)
2. Female patients of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity Limit
70 mg	180 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Joenja is indicated for the treatment of activated PI3Kδ syndrome (APDS). Joenja contains warnings regarding live vaccinations and embryo-fetal toxicity. The safety and effectiveness of Joenja in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Joenja while maintaining optimal therapeutic outcomes.

References

1. Joenja [package insert]. Fallavier, France: Pharming Technologies B.V.; March 2023.

Policy History

Date	Action
April 2023	Addition to PA
June 2023	Annual review
September 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.