BlueCross BlueShield Federal Employee Program

JOENJA
(leniolisib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.

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References

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