

REVUFORJ (revumenib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Revuforj (revumenib) is a menin inhibitor and blocks the interaction of both wild-type lysine methyltransferase 2A (KMT2A) and KMT2A fusion proteins with menin. The binding of KMT2A fusion proteins with menin is involved in KMT2A-rearranged acute leukemias through activation of a leukemogenic transcriptional pathway. In studies, Revuforj demonstrated antiproliferative and antitumor activity in leukemia cells harboring KMT2a fusion proteins (1).

Regulatory Status

FDA-approved indication: Revuforj is a menin inhibitor indicated for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older (1).

Revuforj has a boxed warning for differentiation syndrome, which can be fatal. Signs and symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and renal dysfunction. If differentiation syndrome is suspected, immediately initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution (1).

Revuforj can cause QTc interval prolongation. Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to treatment with Revuforj. Perform an ECG prior to initiation of treatment, and do not initiate in patients with QTcF > 450 msec. Perform an ECG at least once a week for the first 4 weeks on treatment, and at least monthly thereafter (1).

Revuforj can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential and males with female partners of reproductive potential should be advised to use effective contraception during treatment with Revuforj and for 4 months after the last dose (1).

The safety and effectiveness of Revuforj in pediatric patients less than 1 year old have not been established (1).



Federal Employee Program.

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Summary

Revuforj is a menin inhibitor indicated for the treatment of relapsed or refractory acute leukemia with a KMT2A translocation. Revuforj has a boxed warning regarding differentiation syndrome. The safety and effectiveness of Revuforj in pediatric patients less than 1 year old have not been established (1).

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

References

- 1. Revuforj [package insert]. Waltham, MA: Syndax Pharmaceuticals, Inc.; November 2024.
- 2. NCCN Drugs & Biologics Compendium® Revumenib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 28, 2025.