

**IWILFIN
(eflornithine)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Iwilfin (eflornithine) is an irreversible inhibitor of the enzyme ornithine decarboxylase (ODC), the first and rate-limiting enzyme in the biosynthesis of polyamines. Polyamines are involved in differentiation and proliferation of mammalian cells and are important for neoplastic transformation. Inhibition of polyamine synthesis by eflornithine restored the balance of a metabolic pathway involved in regulation of cancer stem cells and glycolytic metabolism and decreased the expression oncogenic drivers of neuroblastoma (1).

Regulatory Status

FDA-approved indication: Iwilfin is an ornithine decarboxylase inhibitor indicated to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy (1).

Iwilfin has been associated with myelosuppression, hepatotoxicity, and hearing loss. Blood counts, liver function tests, and hearing should be monitored before and during treatment with Iwilfin. Withhold, reduce dose, or permanently discontinue based on severity (1).

Iwilfin can cause fetal harm. Females of reproductive potential should be advised to use effective contraception while receiving Iwilfin and for at least 1 week after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Iwilfin and for 1 week after the last dose (1).

The safety and effectiveness of Iwilfin in pediatric patients has been established (1).

Summary

Iwilfin (eflornithine) is an ornithine decarboxylase inhibitor indicated to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB). Iwilfin has been associated with myelosuppression, hepatotoxicity, hearing loss, and embryo-fetal toxicity. The safety and effectiveness of Iwilfin in pediatric patients has been established (1).



Federal Employee Program.

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

References

1. Iwilfin [package insert]. Louisville, KY: USWM, LLC.; December 2023.
2. NCCN Drugs & Biologics Compendium® Eflornithine 2024. National Comprehensive Cancer Network, Inc. Accessed on April 11, 2024.