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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 26, 2024
Subject:	Iwilfin	**Page:**	1 of 4

Last Review Date: March 8, 2024

Iwilfin

Description

Iwilfin (eflornithine)

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).

Related policies
Danyelza, Unituxin

Policy

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

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

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

Prior-Approval Requirements

Diagnosis

Patient must have the following:

High-risk neuroblastoma (HRNB)

AND ALL of the following:

a. Patient has demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy
b. Prescriber agrees to perform complete blood count (CBC), liver function tests (LFTs), and baseline audiogram before initiating and during therapy with Iwilfin
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Iwilfin and for 1 week after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Iwilfin and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

High-risk neuroblastoma (HRNB)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor complete blood count (CBC), liver function tests (LFTs), and audiogram during therapy with Iwilfin
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Iwilfin and for 1 week after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Iwilfin and for 1 week after the last dose

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 1,536 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 1,536 mg per day

Duration 12 months (**ONE renewal ONLY)**

Rationale

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).

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.

Policy History

Date	Action
January 2024	Addition to PA
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.