

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Iwilfin Prior Authorization Policy

- Iwilfin™ (eflornithine tablets – US WorldMeds)

REVIEW DATE: 01/08/2025

OVERVIEW

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

Guidelines

Iwilfin is discussed in the National Comprehensive Cancer Network (NCCN) guidelines. NCCN neuroblastoma guidelines (version 2.2024 – July 2, 2024) recommend Iwilfin as continuation therapy in patients with high-risk disease who have had at least a partial response to prior systemic agents and have completed post-consolidation immunotherapy with Unituxin® (dinutuximab intravenous infusion) [category 2B].²

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Iwilfin. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Iwilfin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Neuroblastoma** Approve for 1 year if the patient meets ALL of the following (A, B and C):
 - A) Patient has high-risk disease; AND
 - B) The medication is being used to reduce the risk of relapse; AND
 - C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.

Note: Examples of anti-glycolipid disialoganglioside (GD2) immunotherapy includes Unituxin® (dinutuximab intravenous infusion).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Iwilfin is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Iwilfin™ tablets [prescribing information]. Louisville, KY: USWM; December 2023.

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2. The NCCN Neuroblastoma Clinical Practice Guidelines in Oncology (version 2.2024 – July 2, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 2, 2025.