

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2026 P 1433-3
Program	Prior Authorization/Notification
Medication	Iwilfin™ (eflornithine)
P&T Approval Date	2/2024, 2/2025, 2/2026
Effective Date	5/1/2026

**1. Background:**

Iwilfin (eflornithine) 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.

**2. Coverage Criteria<sup>a</sup>:**

<p><b>A. <u>Patients less than 19 years of age</u></b></p> <p>1. <b>Iwilfin</b> will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Patient is less than 19 years of age</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>High-Risk Neuroblastoma (HRNB)</u></b></p> <p>1. <b><u>Initial Authorization</u></b></p> <p style="padding-left: 40px;">a. <b>Iwilfin</b> will be approved based on <b>all</b> of the following criteria:</p> <p style="padding-left: 80px;">(1) Diagnosis of high-risk neuroblastoma (HRNB)</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 80px;">(2) Patient has shown at least a partial response to prior multiagent, multimodality therapy</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 80px;">(3) Prior therapy included anti-GD2 immunotherapy [e.g., Danyelza (naxitamab-gqgk), Unituxin (dinutuximab)]</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p>2. <b><u>Reauthorization</u></b></p> <p style="padding-left: 40px;">a. <b>Iwilfin</b> will be approved based on the following criterion:</p>
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(1) Patient does not show evidence of progressive disease while on Iwilfin therapy

**Authorization will be issued for 12 months.**

**C. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Iwilfin [package insert]. USWM, LLC.: Louisville, KY; November 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [www.nccn.org](http://www.nccn.org). Accessed December 16, 2025.

Program	Prior Authorization/Notification – Iwilfin™ (eflornithine)
<b>Change Control</b>	
2/2024	New program.
2/2025	Annual review. No changes to clinical criteria.
2/2026	Annual review. No changes to coverage criteria. Updated reference.