UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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

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[a]:

A. Patients less than 19 years of age

1. **Iwilfin** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. High-Risk Neuroblastoma (HRNB)

1. **Initial Authorization**

   a. **Iwilfin** will be approved based on **all** of the following criteria:

      (1) Diagnosis of high-risk neuroblastoma (HRNB)

      -AND-

      (2) Patient has shown at least a partial response to prior multiagent, multimodality therapy

      -AND-

      (3) Prior therapy included anti-GD2 immunotherapy (e.g., Danyelza (naxitamab-gqgk), Unituxin (dinutuximab))

   Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Iwilfin** will be approved based on the following criterion:

(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.

[a] 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; December 2023.

Program	Prior Authorization/Notification – Iwilfin™ (eflornithine)
Change Control	
2/2024	New program.