# USWM Access Policy for Eflornithine (DFMO)

## United States Patient Access Policy

USWM, LLC (US WorldMeds) is committed to supporting patients by providing safe, fair, and sustainable access to its medicines.

Eflornithine (DFMO, marketed as IWILFIN®) is **FDA-approved in the United States 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.** IWILFIN is commercially available in the United States and may be prescribed by licensed physicians in accordance with applicable laws and regulations.

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**Alternate US Access Pathways**

When commercial access is not possible, the following pathways may be considered:

**1. Clinical Trials (Preferred Pathway)**

Participation in a clinical trial is the preferred pathway for patients seeking access to DFMO for investigational uses.

USWM collaborates with Beat Childhood Cancer Research Consortium (BCC) and Sponsor-Investigator Dr. Giselle Sholler to support clinical development of DFMO, including:

- Ongoing interventional clinical trials in pediatric oncology indications
- A Group Expanded Access Program (Intermediate-Size Population Expanded Access)

Information on the BCC-supported Expanded Access study, including eligibility criteria and site information, is available here: View Expanded Access Study (NCT03581240)

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**2. Expanded Access (Individual Patient Requests — Rare Circumstances)**

In limited and exceptional circumstances, Expanded Access for individual patients (including single-patient IND [spIND] or emergency IND [eIND]) may be considered.

Expanded Access may be appropriate only when all of the following conditions are met:

- The patient has a **serious or life-threatening condition**
- The patient is **not eligible for, or unable to access, an appropriate clinical trial**
- The requested use is **not within the FDA-approved labeling**
- The treating physician determines that the **potential benefit justifies the potential risk**
- Adequate safety and clinical data exist to support the proposed use
- Provision of DFMO will **not interfere with clinical development or commercial supply**

- Sufficient drug supply is available

All requests must be **initiated by a licensed physician** and will be evaluated on a **case-by-case basis**. Expanded Access may not always be available, and submission of a request does not guarantee access.

USWM does not routinely provide Individual Patient Expanded Access outside of these limited circumstances.

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**General Principles**

- Commercial access is the standard pathway for patients within the approved indication
- Participation in clinical trials is the preferred pathway for access outside approved use
- All Expanded Access requests are evaluated on a fair and equitable basis
- USWM cannot guarantee access to DFMO in all cases
- USWM may revise this policy at any time and will make updated versions publicly available

Licensed physicians may submit inquiries to:
**regulatoryaffairs@usworldmeds.com**
USWM will endeavor to acknowledge inquiries within 5 business days.

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## International Patient Access

Eflornithine is commercially available through standard prescribing pathways in Switzerland, Australia, Israel, and in designated medical tourism pilot zones in China.

In countries where DFMO is not commercially approved, access may be available through an international pharmacy program managed in partnership with Tanner Pharma.

Physicians may initiate inquiries at:
**IWILFIN@tannerpharma.com**