Generic Name: eflornithine

Therapeutic Class or Brand Name: Iwilfin

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/15/2024

Date Last Reviewed / Revised: 5/7/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of the following FDA-approved diagnosis A. AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Pediatric or adult patient with a documented diagnosis of high-risk neuroblastoma (HRNB).

i. Documentation of at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy such as Unituxin (dinutuximab).

ii. Documented recent weight and height for BSA dosage calculation.

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Two-hundred forty 192mg tablets/30 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease. Maximum length of treatment is 2 years.

APPENDIX

Recommended Dose by BSA

BSA (m^2)	Recommended Dose	Reduced Dose for Toxicity Management	Dose for Severe Renal Impairment (eGFR <30 mL/min)
>1.5	768 mg (4 tablets) orally twice a day	576 mg (3 tablets) orally twice a day	384 mg (2 tablets) orally twice a day
0.75 to 1.5	576 mg (3 tablets) orally twice a day	384 mg (1 tablets) orally twice a day	384 mg (2 tablets) in the morning and 192 mg (1 tablet) in the evening
0.5 to < 0.75	384 mg (2 tablets) orally twice a day	192 mg (1 tablet) orally twice a day	192 mg (1 tablet) orally twice a day
0.25 to < 0.5	192 mg (1 tablet) orally twice a day	192 mg (1 tablet) orally once a day	192 mg (1 tablet) once a day

REFERENCES

1. Iwilfin. Prescribing Information. US World Meds. November 2024. Accessed May 7, 2026. https://www.dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6716d8cc-66e6-4cee-935c-ccb85ed984f5
2. Oesterheld J, Ferguson W, Kraveka JM, et al. Eflornithine as postimmunotherapy maintenance in high-risk neuroblastoma: externally controlled, propensity score-matched survival outcome comparisons. *J Clin Oncol*. 2024;42(1):90-102. doi: 10.1200/JCO.22.02875.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Neuroblastoma. Version 2.2026. Updated *April 28, 2026*. Accessed *May 7, 2026*.