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: 9/15/2024

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following diagnoses 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 (e.g., Danyelza (naxitamab-gqgk), Unituxin (dinutuximab)).

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

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

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

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

- Reauthorization: 6 months with documentation of tumor response showing stabilization of disease or decrease in tumor spread/size and documentation that patient has not experienced unacceptable medication-related toxicity.
- Maximum length of treatment: 2 years

APPENDIX

Recommended Dose by BSA

BSA (m^2)	Initial Dosage	Reduced Dose for Toxicity Management
>1.5	768 mg (4 tablets) orally twice a day	576 mg (three tablets) orally twice a day
0.75 to 1.5	576 mg (three tablets) orally twice a day	384 mg (two tablets) orally twice a day
0.5 to < 0.75	384 mg (two tablets) orally twice a day	192 mg (one tablet) orally twice a day
0.25 to < 0.5	192 mg (one tablet) orally twice a day	192 mg (one tablet) orally once a day

REFERENCES

1. Iwilfin. Prescribing Information. US WorldMeds. December 2023. Accessed September 14, 2024. https://hcp.iwilfin.com/wp-content/uploads/2024/01/iwilfin_PI-and-PPI_letter.pdf
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. Neuroblastoma. Version 2.2024. Accessed September 15, 2024. https://www.nccn.org/professionals/physician_gls/pdf/neuroblastoma.pdf