VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Iwilfin Prior Authorization Policy
- Iwilfin™ (eflornithine tablets – US WorldMeds)

REVIEW DATE: 01/03/2024

OVERVIEW

Iwilfin, an ornithine decarboxylase inhibitor, is indicated to reduce the risk of relapse in high-risk neuroblastoma in adults and pediatric patients with who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-glycolipid disialoganglioside (GD2) immunotherapy.[1]

Guidelines

Iwilfin is not addressed in the National Comprehensive Cancer Network (NCCN) guidelines. NCCN does not have neuroblastoma clinical practice guidelines. The treatment of high risk neuroblastoma is divided into three phases: induction, consolidation, and post-consolidation.[2] In the induction phase, treatment includes multiagent chemotherapy, peripheral blood stem cell harvest, and surgical resection of the primary site. In the consolidation phase, treatment includes high-dose chemotherapy, autologous stem cell transplantation (ASCT), and radiation or radiotherapy. In the post-consolidation phase, treatment includes anti-GD2 immunotherapy (Unituxin® [dinutuximab intravenous infusion]) in combination with isotretinoin, interleukin-2, and granulocyte-macrophage colony-stimulating factor. For patients who have recurrent or refractory neuroblastoma, treatment options include clinical trial, chemotherapy combined with immunotherapy (e.g. temozolomide, irinotecan, and Unituxin), iodine-131 meta-iodobenzylguanidine alone or in combination with other therapy, or followed by stem cell rescue, novel therapies, chemotherapy, or immunotherapy (e.g. Danyelza® [naxitamab-gqgk intravenous infusion]).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Iwilfin. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Iwilfin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Neuroblastoma** Approve for 1 year if the patient meets the following (A, B and C):
   - **A)** Patient has high-risk disease; AND
   - **B)** The medication is being used to reduce the risk of relapse; AND
   - **C)** Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.
     Note: Examples of anti-glycolipid disialoganglioside (GD2) immunotherapy includes Unituxin® (dinutuximab intravenous infusion).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Iwilfin is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Iwilfin™ tablets [prescribing information]. Louisville, KY: USWM; December 2023.
2. National Cancer Institute: PDQ® Neuroblastoma treatment. National Cancer Institute. Date last modified: August 22, 2023. Available at http://www.cancer.gov/cancertopics/pdq/treatment/neuroblastoma/HealthProfessional. Accessed on December 22, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/03/2024