PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/03/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Iwilfin™ (eflornithine tablets [US WorldMeds])**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Iwilfin™ (eflornithine tablets [US WorldMeds])**

is(are) considered experimental, investigational, or unproven for ANY other use(s); 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