PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/21/2026

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 discussed in the National Comprehensive Cancer Network (NCCN) guidelines. NCCN neuroblastoma guidelines (version 1.2025 – April 16, 2025) recommend Iwilfin as continuation therapy in patients with high-risk disease who have had at least a partial response to prior systemic agents and have completed post-consolidation immunotherapy with Unituxin® (dinutuximab intravenous infusion) [category 2B].[2]

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 ALL of 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 not medically necessary for ANY other use(s); criteria will be updated as new published data are available)

REFERENCES

1. Iwilfin™ tablets [prescribing information]. Louisville, KY: USWM; November 2024.
2. The NCCN Neuroblastoma Clinical Practice Guidelines in Oncology (version 1.2025 – April 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 16, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/03/2024
Annual Revision	No criteria changes.	01/08/2025
Annual Revision	No criteria changes.	01/21/2026