# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Revuforj Prior Authorization Policy
- Revuforj™ (revumenib tablets – Syndax)

**REVIEW DATE:** 11/20/2024

***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

Revuforj, a menin inhibitor, is indicated for the treatment of **relapsed or refractory acute leukemia with a lysine methyltransferase 2A (*KMT2A*) gene translocation** in adults and pediatric patients ≥ 1 year of age.[1]

### Disease Overview

Acute leukemia encompasses acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and mixed phenotype leukemia.[2,3] *KMT2A* rearrangements occur in approximately 5% to 10% of patients with newly diagnosed AML, 10% of patients with ALL, and 8% of patients with mixed phenotypic acute leukemia.[2] Prognosis of acute leukemias with *KMT2A* rearrangements is poor; 5-year overall survival is < 25%.[3]

### Guidelines

Revuforj is not addressed by the National Comprehensive Cancer Network.

### POLICY STATEMENT

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

- **Revuforj™ (revumenib tablets – Syndax)**

**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. **Acute Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   **A)** Patient is ≥ 1 year of age; AND
   **B)** Patient meets ONE of the following (i or ii):
      **i.** Patient has relapsed disease; OR
      **ii.** Patient has refractory disease; AND
   **C)** The disease is positive for a lysine methyltransferase 2A (*KMT2A*) gene translocation.

## CONDITIONS NOT COVERED

- **Revuforj™ (revumenib tablets – Syndax)**

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

## REFERENCES


1. Revuforj™ [prescribing information]. Waltham MA: Syndax; November 2024.
2. Salman MY, Stein EM. Revumenib for patients with acute leukemia: a new tool for differentiation therapy. *Haematologica*. 2024; 109:3488-3495.
3. Issa GC, Aldoss I, Dipersio J, et al. The menin inhibitor ruvemenib in *KMT2A*-rearrranged or *NPM1*-mutant leukemia. *Nature*. 2023; 615:920-924.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | -- | 11/20/2024 |


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