VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/20/2024

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 addressed in National Comprehensive Cancer Network (NCCN) guidelines:[4-6]
- **ALL:** Guidelines (version 3.2024 – December 20, 2024) recommend Revuforj as an "Other Recommended Regimen" for patients with relapsed/refractory *KMT2A*-rearranged Philadelphia chromosome-negative ALL and for patients with relapsed/refractory *KMT2A*-rearranged T-cell ALL (both are category 2A recommendations).
- **Pediatric ALL:** Guidelines (version 2.2025 – December 16, 2024) recommend Revuforj as an "Other Recommended Regimen" for patients with relapsed/refractory *KMT2A*-rearranged BCR::ABL1-negative ALL and for patients with relapsed/refractory *KMT2A*-rearranged T-cell ALL (both are category 2A recommendations).
- **AML:** Guidelines (version 1.2025 – December 20, 2024) recommend Revuforj for the treatment of patients (≥ 18 years of age) with relapsed/refractory *KMT2A*-rearranged AML (category 2A recommendation).

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Revuforj is recommended in those who meet the following criteria:

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 RECOMMENDED FOR APPROVAL
Coverage of Revuforj 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. 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 revumenib in *KMT2A*-rearrranged or *NPM1*-mutant leukemia. *Nature*. 2023;615:920-924.
4. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 24, 2024.
5. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – December 16, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 24, 2024.
6. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 24, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/20/2024
DEU Update	12/24/2024: The Guidelines section has been updated with National Comprehensive Cancer Network (NCCN) recommendations for acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and pediatric ALL; all of which address Revuforj.	--