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 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.

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 ruvemenib in *KMT2A*-rearrranged or *NPM1*-mutant leukemia. *Nature*. 2023;615:920-924.