

Generic Name: Revumenib

Preferred: N/A

Therapeutic Class or Brand Name: N/A

Non-preferred: N/A

Applicable Drugs: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:
FDA-Approved Indication(s)
 - A. Acute Leukemia
 - i. Documentation of lysine methyltransferase 2A gene (KMT2A) translocation
 - ii. Documentation of relapsed or refractory disease
 - iii. Revuforj will be used as a single agent
 - iv. If < 18 years old, documented reason of why patient is ineligible for clinical trial.
- II. Minimum age requirement: 1 year old and older
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Acute promyelocytic leukemia (APL)
- Philadelphia chromosome positive B-cell ALL

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity is limited to a 30-day supply

- Tablets: 25 mg, 110 mg, 160 mg

Table 1: Revuforj dose for patients 1 year old and older

Patient weight	Without strong CYP3A4 Inhibitors	With Strong CYP3A4 Inhibitors
40 kg or more	270 mg orally twice daily	160 mg orally twice daily
Less than 40 kg	160 mg/m ² orally twice daily*	95 mg/m ² orally twice daily*

* See table 2 for total tablet dosage by BSA (body surface area) for patients weighing < 40 kg

Table 2: Revuforj recommended dose using tablets for patients weighing less than 40 kg

BSA (m ²)	Dosage for 160 mg/m ²	Dosage for 95 mg/m ²
1.4	220 mg twice daily	135 mg twice daily
1.3	220 mg twice daily	135 mg twice daily
1.2	185 mg twice daily	110 mg twice daily
1.1	185 mg twice daily	110 mg twice daily
1	160 mg twice daily	100 mg twice daily
0.9	135 mg twice daily	75 mg twice daily
0.8	135 mg twice daily	75 mg twice daily
0.7	110 mg twice daily	50 mg twice daily
0.6	100 mg twice daily	50 mg twice daily
0.5	75 mg twice daily	50 mg twice daily
0.4	50 mg twice daily	25 mg twice daily

APPROVAL LENGTH

- Authorization:** 4 months
- Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

- Revuforj. Prescribing Information. Syndax Pharmaceuticals, Inc. November 2024. Accessed April 3, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2024/218944s000lbl.pdf
- National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Acute Lymphoblastic Leukemia. Version 3.2025. Updated March 17, 2025. Accessed April 3, 2025. www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf

3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia. Version 3.2024. Updated December 20, 2024. Accessed April 3, 2025. www.nccn.org/professionals/physician_gls/pdf/all.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. Version 2.2025. Updated January 27, 2025. Accessed April 3, 2025. www.nccn.org/professionals/physician_gls/pdf/aml.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.