



## 5.21.232

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	December 6, 2024
<b>Subject:</b>	Revuforj	<b>Page:</b>	1 of 4

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**Last Review Date:** March 6, 2026

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## Revuforj

### Description

#### Revuforj (revumenib)

#### Background

Revuforj (revumenib) is a menin inhibitor and blocks the interaction of both wild-type lysine methyltransferase 2A (KMT2A) and KMT2A fusion proteins with menin. The binding of KMT2A fusion proteins with menin is involved in nucleophosmin 1 (*NPM1*) mutated acute myeloid leukemias and KMT2A-rearranged acute leukemias, respectively, through activation of a leukemogenic transcriptional pathway. In studies, Revuforj demonstrated antiproliferative and antitumor activity in leukemia cells harboring KMT2a fusion proteins and showed antiproliferative activity in vitro in leukemia cells with an *NPM1* mutation (1).

#### Regulatory Status

FDA-approved indication: Revuforj is a menin inhibitor indicated for: (1)

- the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation as determined by an FDA-authorized test in adult and pediatric patients 1 year and older.
- the treatment of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation in adult and pediatric patients 1 year and older who have no satisfactory alternative treatment options.

Revuforj has a boxed warning for differentiation syndrome, which can be fatal. Signs and symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and renal dysfunction. If

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<b>Subject:</b>	Revuforj	<b>Page:</b>	2 of 4

---

differentiation syndrome is suspected, immediately initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution (1).

Revuforj also has a boxed warning for QTc interval prolongation and Torsades de Pointes. Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to and during treatment with Revuforj. Perform an ECG prior to initiation of treatment, and do not initiate in patients with QTcF > 450 msec. Perform an ECG at least once a week for the first 4 weeks on treatment, and at least monthly thereafter (1).

Revuforj can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential and males with female partners of reproductive potential should be advised to use effective contraception during treatment with Revuforj and for 4 months after the last dose (1).

The safety and effectiveness of Revuforj in pediatric patients less than 1 year old have not been established (1).

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## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Revuforj may be considered **medically necessary** if the conditions indicated below are met.

Revuforj may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 1 year of age or older

### Diagnosis

Patient must have the following:

1. Relapsed or refractory acute leukemia
  - a. Presence of lysine methyltransferase 2A gene (KMT2A) translocation in bone marrow cells, as determined by an FDA-authorized test
2. Relapsed or refractory acute myeloid leukemia (AML)

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	December 6, 2024
<b>Subject:</b>	Revuforj	<b>Page:</b>	3 of 4

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- a. Susceptible nucleophosmin 1 (*NPM1*) mutation
- b. Patient has no satisfactory alternative treatment options

**AND ALL** of the following:

- a. Prescriber agrees to correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to treatment
- b. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome
- c. Prescriber agrees to monitor for QTc interval prolongation
- d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revuforj and for 4 months after the last dose
- e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revuforj and for 4 months after the last dose

## Prior – Approval *Renewal* Requirements

**Age** 1 year of age or older

### Diagnosis

Patient must have the following:

1. Relapsed or refractory acute leukemia
2. Relapsed or refractory acute myeloid leukemia (AML)

**AND ALL** of the following:

- a. **NO** disease progression or unacceptable toxicity
- b. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome
- c. Prescriber agrees to monitor for QTc interval prolongation
- d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revuforj and for 4 months after the last dose
- e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revuforj and for 4 months after the last dose

### Policy Guidelines

## Pre - PA Allowance

None

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	December 6, 2024
<b>Subject:</b>	Revuforj	<b>Page:</b>	4 of 4

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## Prior - Approval Limits

**Quantity** 540 mg per day

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Revuforj is a menin inhibitor indicated for the treatment of relapsed or refractory acute leukemia with a KMT2A translocation and relapsed or refractory AML with a susceptible *NPM1* mutation. Revuforj has a boxed warning regarding differentiation syndrome and QTc prolongation/Torsades de Pointes. The safety and effectiveness of Revuforj in pediatric patients less than 1 year old have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Revuforj while maintaining optimal therapeutic outcomes.

### References

1. Revuforj [package insert]. Waltham, MA: Syndax Pharmaceuticals, Inc.; October 2025.
2. NCCN Drugs & Biologics Compendium® Revumenib 2026. National Comprehensive Cancer Network, Inc. Accessed on January 12, 2026.

## Policy History

Date	Action
December 2024	Addition to PA
March 2025	Annual review and reference update
November 2025	Per PI update, added indication of relapsed or refractory AML with a susceptible NPM1 mutation
March 2026	Annual review and reference update

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**

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<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	December 6, 2024
<b>Subject:</b>	Revuforj	<b>Page:</b>	5 of 4

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