BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

REVUFORJ™ (revumenib) oral
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for REVUFORJ (revumenib)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Oncologist or is in consultation with an Oncologist

Indication
- Relapsed or refractory acute leukemia with lysine methyltransferase 2A gene (KMT2A) translocation
- Other oncologic direct treatment uses listed in National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

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Age Requirement
- 1 year of age or older with a body surface area of at least 0.4 meters squared

Baseline Clinical Evaluation
- Documentation of KMT2A translocation in bone marrow cells
- No 11q23 partial tandem duplication
- White blood cell count less than 25 giga per liter
- Corrected serum electrolyte abnormalities including hypokalemia and hypomagnesemia if present
- Electrocardiogram showing QTcF less than 450 milliseconds
- Liver enzyme evaluation
- Negative pregnancy test within 7 days prior to starting therapy for women of reproductive potential

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Concomitant use of strong or moderate CYP3A4 inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin)
  - Severe renal impairment (creatinine clearance less than 30 milliliters per minute) or end stage renal disease (creatinine clearance less than 15 milliliters per minute)
  - Severe hepatic disease (total bilirubin greater than 3 times the upper limit of normal and any aspartate aminotransferase elevation)

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results (KMT2A translocation, white blood cell count, electrolytes, QTcF, liver enzymes, pregnancy test)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualifications
- Continues to be seen by an Oncologist or is in consultation with an Oncologist

Clinical Response
- **TWO** of the following:
  - No evidence of disease progression or unacceptable drug toxicity

- Achieved morphological leukemia free state by 4 cycles of treatment
- Achieved transfusion independence
- Did not require hematopoietic stem cell transplantation

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Concomitant use of strong or moderate CYP3A4 inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin)
  - Severe renal impairment (creatinine clearance less than 30 milliliters per minute) or end stage renal disease (creatinine clearance less than 15 milliliters per minute)
  - Severe hepatic disease (total bilirubin greater than 3 times the upper limit of normal and any aspartate aminotransferase elevation)
  - QTc interval prolongation with life threatening arrhythmia
  - Severe nonhematologic adverse effect recurring after dose reduction
  - Severe or life threatening allergic reaction

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in the given indication
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

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Description:

Revuforj (revumenib) is a menin inhibitor indicated for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

WBC expressed as Gi/L:
Gi/L" typically stands for "giga per liter," which is a unit of measurement used in scientific fields, particularly when discussing very large quantities of particles per liter of a solution; in medical contexts, it often refers to a count of cells, for example white blood cells or platelets, expressed as billions per liter of blood.

Resources:

Revuforj (revumenib) product information, revised by Syndax Pharmaceuticals, Inc. 04-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 29, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Lymphoblastic Leukemia Version 2.2025 – Updated June 27, 2025. Available at https://www.nccn.org. Accessed January 29, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Pediatric Acute Lymphoblastic Leukemia Version 1.2026 – Updated August 11, 2025. Available at https://www.nccn.org. Accessed January 29, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Myeloid Leukemia Version 3.2026 – Updated November 24, 2025. Available at https://www.nccn.org. Accessed January 29, 2026.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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