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 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.

Criteria:

- **Criteria for initial therapy:** Revuforj (revumenib) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual is 1 year of age or older

  3. Individual has a confirmed diagnosis of **ONE** of the following:
     a. Relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation

b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

4. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
   a. There is documentation of the presence of a KMT2A translocation in bone marrow cells
   b. Individual does not have 11q23 partial tandem duplication
   c. The WBC is less than 25 Gi/L (see Definitions section)
   d. Correct serum electrolytes abnormalities including hypokalemia and hypomagnesemia if present
   e. ECG documenting QTcF is less than 450 msec
   f. Liver enzymes
   g. There is documentation of a negative pregnancy test in a woman of reproductive potential within 7 days prior to starting therapy

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual is not currently taking any other drugs which cause severe adverse reactions or any significant drug interactions requiring discontinuation such as strong or moderate CYP3A4 inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin, others)

7. The individual does not have severe renal impairment (CrCl less than 30 mL/min) or end-stage renal disease (CrCl less than 15 mL/min)

8. Individual does not have severe hepatic disease (total bilirubin greater than 3 times the upper limit of normal and any aspartate aminotransferase)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Revuforj (revumenib) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

2. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
   a. There is no evidence of disease progression or unacceptable drug toxicity
   b. Achieved morphological leukemia-free state by 4 cycles of treatment
   c. Did not require hematopoietic stem cell transplantation (HSCT)
   d. Achieved transfusion independence

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. QTc interval prolongation with signs/symptoms of life-threatening arrhythmia, Torsades de pointes, polymorphic ventricular tachycardia, signs/symptoms of life-threatening arrhythmia
    b. Any severe nonhematologic adverse effect that recurs after withholding dose and restart with a dose reduction
    c. Severe or life-threatening allergic reaction

6. Individual is not currently taking any other drugs which cause severe adverse reactions or any significant drug interactions requiring discontinuation such as rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin, others

7. The individual does not have severe renal impairment (CrCl less than 30 mL/min) or end-stage renal disease (CrCl less than 15 mL/min)

8. Individual does not have severe hepatic disease (total bilirubin greater than 3 times the upper limit of normal and any aspartate aminotransferase)

Renewal duration: 12 months

- 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**

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

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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. 11-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 26, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Lymphoblastic Leukemia Version 3.2024 – Updated December 20, 2024. Available at https://www.nccn.org. Accessed December 26, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Pediatric Acute Lymphoblastic Leukemia Version 2.2025 – Updated December 16, 2024. Available at https://www.nccn.org. Accessed December 26, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Myeloid Leukemia Version 1.2025 – Updated December 20, 2024. Available at https://www.nccn.org. Accessed December 26, 2024.

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.