BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

REZLIDHIA™ (olutasidenib) 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 REZLIDHIA (olutasidenib)

Criteria for Initial Therapy:

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

Indication
- Relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase 1 (IDH1) mutation
- Other oncologic direct treatment uses listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

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Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Presence of IDH1 mutation in blood or bone marrow
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2
- Complete blood count
- Blood chemistry including liver function tests

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:
  - Severe renal impairment (creatinine clearance less than 30 mL/min estimated by Cockcroft Gault), kidney failure (creatinine clearance less than 15 mL/min), or dialysis
  - Severe hepatic impairment (total bilirubin greater than 3 times upper limit of normal with any AST)
  - Concomitant use with strong or moderate CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin)

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results (IDH1 mutation, ECOG status, CBC, liver function tests)
  - 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 Qualification
- Continues to be seen by an Oncologist or is in consultation with an Oncologist

Clinical Response
- No evidence of disease progression or unacceptable toxicity

Adherence
- Adherence to the prescribed therapy regimen has been documented

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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:
  - Severe renal impairment (creatinine clearance less than 30 mL/min estimated by Cockcroft Gault), kidney failure (creatinine clearance less than 15 mL/min), or dialysis
  - Severe hepatic impairment (total bilirubin greater than 3 times upper limit of normal with any AST)
  - Concomitant use with strong or moderate CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin)
  - Life threatening hepatotoxicity or severe/serious hepatotoxicity that recurs after dose interruption or dose reduction
  - Other life threatening or severe/serious toxicity thought to be drug induced that recurs after dose interruption or dose reduction

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm 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

Description:

Rezlidhia (olutasidenib) is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.

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Definitions:

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

Resources:

Rezlidhia (olutasidenib) cap product information, revised by Rigel 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 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.