

Applicable Drugs: Rezlidhia (olutasidenib)

Preferred: N/A

Non-preferred: olutasidenib (Rezlidhia)

Date of Origin: 8/28/2023

Date Last Reviewed / Revised: 5/13/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

- I. Documented diagnosis of relapsed or refractory acute myeloid leukemia (AML).
- II. Documentation of susceptible *IDH1* mutation as detected by an FDA-approved test.
- III. Age: ≥ 18 years old.
- IV. Treatment must be prescribed by or in consultation with an oncologist.
- V. Request is for a medication with the appropriate FDA labeling and dosage, or its use is supported by current clinical practice guidelines.
- VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Previous treatment failure with olutasidenib (Rezlidhia).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 150 mg dose/day: Thirty 150 mg capsules per 30 days.
- 300 mg dose/day: Sixty 150 mg capsules per 30 days.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective and well-tolerated (e.g., no disease progression or unacceptable toxicity).

APPENDIX

N/A

REFERENCES

1. Rezlidhia. Prescribing information. Rigel Pharmaceuticals, Inc.; 2024. Accessed May 13, 2025. <https://www.rezlidhiahcp.com/downloads/pdf/REZLIDHIA-Full-Prescribing-Information.pdf>
2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia (Version 2.2025). https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed May 13, 2025.
3. De Botton S, Fenaux P, Yee K, et al. Olutasidenib (FT-2102) induces durable complete remissions in patients with relapsed or refractory IDH1-mutated AML. *Blood Adv*. 2023;7(13):3117-3127. doi: 10.1182/bloodadvances.2022009411

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.