

Generic Name: olutasidenib

Applicable Drugs: Rezlidhia

Preferred: N/A

Non-preferred: olutasidenib (Rezlidhia)

Date of Origin: 8/28/2023

Date Last Reviewed / Revised: 08/28/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V 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. Medication dose, plan for appropriate monitoring, and/or dose adjustment(s) consistent with FDA labeling.
- V. 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 with olutasidenib (if administered continuously).

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 documentation of the absence of disease progression or unacceptable toxicity.

APPENDIX

N/A

REFERENCES

1. Rezlidhia. Prescribing information. Rigel Pharmaceuticals, Inc.; 2022. Accessed July 16, 2023. <https://www.rezlidhiahcp.com/downloads/pdf/REZLIDHIA-Full-Prescribing-Information.pdf>
2. 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
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia. V.4.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed July 16, 2023.

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.