PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rezlidhia Prior Authorization Policy
- Rezlidhia™ (olutasidenib capsules – Rigel)

REVIEW DATE: 12/13/2023

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network (NCCN) acute myeloid leukemia guidelines (version 6.2023 – October 24, 2023) recommend Rezlidhia or Tibsovo® (ivosidenib tablets) for patients with relapsed or refractory AML with an *IDH1* mutation (both category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rezlidhia. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rezlidhia is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or refractory disease; AND
   - **C)** Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation positive disease as detected by an approved test.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rezlidhia is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rezlidhia™ capsules [prescribing information]. San Francisco, CA: Rigel; December 2022.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 6.2023 – October 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 1, 2023.