PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/13/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Rezlidhia™ (olutasidenib capsules (Rigel)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

Rezlidhia™ (olutasidenib capsules (Rigel)
is(are) considered experimental, investigational or unproven for ANY other use(s).

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/14/2022
Update	**1/17/2023**: The guidelines section was updated to reflect updated guideline recommendations that include Rezlidhia.	--
Annual Revision	No criteria changes.	12/13/2023