UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1403-2
Program	Prior Authorization/Notification
Medication	Rezlidhia™ (olutasidenib)
P&T Approval Date	2/2023, 2/2024
Effective Date	5/1/2024

1. Background:
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.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Rezlidhia** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Acute Myeloid Leukemia (AML)

1. **Initial Authorization**

   a. **Rezlidhia** will be approved based on **all** of the following criteria:

   (1) Diagnosis of acute myeloid leukemia (AML)

   -AND-

   (2) Positive for a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (e.g., R132C, R132H, R132G, R132S, R132L)

   -AND-

   (3) Disease is relapsed or refractory

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Rezlidhia** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Rezlidhia** therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Rezlidhia [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; December 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed December 27, 2023.

Program	Prior Authorization/Notification – Rezlidhia (olutasidenib)
Change Control	
2/2023	New program.
2/2024	Annual review with no change to coverage criteria. Updated reference.