

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2026 P 1403-4
Program	Prior Authorization/Notification
Medication	Rezlidhia™ (olutasidenib)
P&T Approval Date	2/2023, 2/2024, 2/2025, 2/2026
Effective Date	5/1/2026

**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.

The National Cancer Comprehensive Network (NCCN) guideline also recommends the use of Rezlidhia for lower-intensity treatment induction in patients to treat AML with a susceptible IDH1 mutation who are not a candidate for intensive induction therapy or declines and in myelodysplastic syndromes (MDS) 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<sup>a</sup>:**

<p><b>A. <u>Patients less than 19 years of age</u></b></p> <p>1. <b>Rezlidhia</b> will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Patient is less than 19 years of age</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Acute Myeloid Leukemia (AML)</u></b></p> <p>1. <b><u>Initial Authorization</u></b></p> <p style="padding-left: 40px;">a. <b>Rezlidhia</b> will be approved based on <b><u>all</u></b> of the following criteria:</p> <p style="padding-left: 80px;">(1) Diagnosis of acute myeloid leukemia (AML)</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 80px;">(2) Positive for a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (e.g.,</p>
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R132C, R132H, R132G, R132S, R132L)

-AND-

(3) **One** of the following:

- (a) Disease is relapsed or refractory
- (b) Patient is not a candidate for or declines intensive induction therapy

**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. **Myelodysplastic Syndromes (MDS)**

1. **Initial Authorization**

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

- (1) Diagnosis of myelodysplastic syndrome (MDS)

-AND-

- (2) Presence of IDH1 mutation

**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.**

D. **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.**

<sup>a</sup> 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.; April 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [www.nccn.org](http://www.nccn.org). Accessed January 7, 2025.

Program	Prior Authorization/Notification – Rezlidhia (olutasidenib)
<b>Change Control</b>	
2/2023	New program.
2/2024	Annual review with no change to coverage criteria. Updated reference.
2/2025	Annual review. Added criteria for Myelodysplastic Syndromes (MDS) per NCCN. Updated background and references.
2/2026	Annual review. Added criteria for lower-intensity treatment induction in patients to treat AML with a susceptible IDH1 mutation who are not a candidate for intensive induction therapy or declines per NCCN. Updated background and references.