Commercial/Healthcare Exchange PA Criteria

Effective: February 9, 2023

Prior Authorization: Rezlidhia

Products Affected: Rezlidhia (olutasidenib) oral capsules

Medication Description: Rezlidhia is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. Olutasidenib is a small molecule inhibitor of mutated isocitrate dehydrogenase-1 (IDH-1), such as R132H and R132C substitutions, which can lead to increased levels of 2-hydroxyglutarate in leukemia cells. Efficacy is measured by clinically meaningful disease remission with olutasidenib use and/or inhibition of mutant IDH-1 enzymatic activity at olutasidenib concentrations attained by the recommended dosage.

Covered Uses:

1. Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Prescence of isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

Prescriber Restriction: Prescribed by, or in consultation with, an oncologist

Age Restriction: 18 years or older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Acute Myeloid Leukemia.** Approve 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.

References:

1. Rezlidhia™ capsules [prescribing information]. San Francisco, CA: Rigel; December 2022

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/09/2023