BlueCross BlueShield Federal Employee Program

REZLIDHIA
(olutasidenib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Rezlidhia (olutasidenib) is a small-molecule inhibitor of mutated isocitrate dehydrogenase-1 (IDH1). In patients with acute myeloid leukemia (AML), susceptible IDH1 mutations are defined as those leading to increased levels of 2-hydroxyglutarate (2-HG) in the leukemia cells and where efficacy is predicted by clinically meaningful remissions with the recommended dose of Rezlidhia and/or inhibition of mutant IDH1 enzymatic activity at concentrations of Rezlidhia sustainable at the recommended dosage according to validated methods. The most common of such mutations in patients with AML are R132H and R132C substitutions (1).

Regulatory Status

FDA-approved indication: Rezlidhia 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 as detected by an FDA-approved test (1).

Rezlidhia has a boxed warning for differentiation syndrome, which can be fatal if not treated. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells. Symptoms of differentiation syndrome in patients treated with Rezlidhia included leukocytosis, dyspnea, pulmonary infiltrates/pleuropericardial effusion, kidney injury, fever, edema, pyrexia, and weight gain. If differentiation syndrome is suspected, withhold Rezlidhia, initiate systemic corticosteroids and hemodynamic monitoring until symptom resolution (1).

Patients treated with Rezlidhia can develop hepatotoxicity, presenting as increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased blood alkaline phosphatase, and/or elevated bilirubin. Liver function tests should be obtained at baseline and periodically during treatment with Rezlidhia (1).

The safety and effectiveness of Rezlidhia in pediatric patients less than 18 years of age have not been established (1).

Summary

Rezlidhia 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 as detected by an FDA-approved test. Rezlidhia has a boxed warning regarding differentiation syndrome. The safety and effectiveness of Rezlidhia in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rezlidhia while maintaining optimal therapeutic outcomes.

References

1. Rezlidhia [package insert]. Greenville, NC: Metrics Contract Services; April 2024.
2. NCCN Drugs & Biologics Compendium® Olutasidenib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.