BlueCross BlueShield Federal Employee Program

IDHIFA (enasidenib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Idhifa is an oral cancer agent that inhibits isocitrate dehydrogenase-2 (IDH2). Idhifa is indicated for the treatment of acute myeloid leukemia (AML) which is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow (1).

Regulatory Status

FDA-approved indication: Idhifa is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test (1).

Idhifa has a boxed warning for differentiation syndrome which may be life-threatening if not treated. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells. While there is no diagnostic test for differentiation syndrome, symptoms in patients treated with Idhifa included acute respiratory distress represented by dyspnea and/or hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, lymphadenopathy, bone pain, and hepatic, renal, or multi-organ dysfunction (1).

Safety and efficacy in pediatric patients below the age of 18 have not been established (1).

Summary

Idhifa is indicated for the treatment of acute myeloid leukemia (AML) which is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow. Safety and efficacy in pediatric patients below the age of 18 have not been established (1).

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

References

1. Idhifa [package insert]. Princeton, NJ: Bristol-Myers Squibb company; December 2024.
2. NCCN Drugs & Biologics Compendium® Enasidenib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.