

Clinical Pharmacy Program Guidelines for Idhifa

Program	Prior Authorization
Medication	Idhifa [®] (enasidenib)
Issue Date	9/2017
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Idhifa[®] (enasidenib) 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.

2. Coverage Criteria:

<p>A. <u>Acute Myeloid Leukemia (AML)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Idhifa will be approved based on all of the following criteria:</p> <p>(1) Diagnosis of acute myeloid leukemia (AML)</p> <p style="text-align: center;">-AND-</p> <p>(2) Disease is relapsed or refractory</p> <p style="text-align: center;">-AND-</p> <p>(3) AML is IDH2 mutation-positive</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Idhifa will be approved based on the following criterion:</p> <p>(1) Patient does not show evidence of progressive disease while on Idhifa therapy</p>

Authorization will be issued for 12 months.

3. References:

1. Idhifa [package insert]. Cambridge, MA: Celgene Corporation; August 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed August 7, 2017.

Program	Prior Authorization –Idhifa (enasidenib)
Change Control	
Date	Change
9/2017	New program