

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

## Idhifa (enasidenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Idhifa (enasidenib)	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Idhifa (enasidenib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory acute myeloid leukemia (AML); **AND**
- II. Individual has an isocitrate dehydrogenase-2 (IDH2) mutation with test results confirmed;

#### **OR**

- III. Individual has a diagnosis of acute myeloid leukemia (AML); **AND**
- IV. Individual is using as treatment induction therapy; **AND**
- V. Individual is  $\geq 60$  years of age and cannot use more intensive remission induction therapy; **AND**
- VI. Individual has an isocitrate dehydrogenase-2 (IDH2) mutation with test results confirmed (NCCN 2A).

#### **Note:**

Idhifa has a black box warning for differentiation syndrome which can be fatal if not treated. If differentiation syndrome is suspected, corticosteroid therapy and hemodynamic monitoring should be initiated and continued until symptom resolution.

#### Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 19, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. Stein EM, Shoben A, Borate U, et al. Enasidenib is Highly Active in Previously Untreated IDH2 Mutant AML: Early Results from the Beat AML Master Trial. Blood 2018; 132:287.

<b>Market Applicability</b>						
<b>Market</b>	<b>GA</b>	<b>KY</b>	<b>MD</b>	<b>NJ</b>	<b>NY</b>	<b>WA</b>
<b>Applicable</b>	X	X	X	X	X	X

6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 19, 2020.
- a. Acute Myeloid Leukemia. V3.2020. Revised December 23, 2019.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.