

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 (Label);

OR

- III. Individual has a diagnosis of acute myeloid leukemia (AML); **AND**
 - IV. Individual has an isocitrate dehydrogenase-2 (IDH2) mutation with test results confirmed (NCCN 2A); **AND**
 - V. Individual is using as treatment induction therapy; **AND**
 - VI. Individual cannot use intensive remission induction therapy;
- ### **OR**
- VII. Individual is using as consolidation therapy as continuation of low-intensity regimen used for induction therapy.

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.: 2022. 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 20, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Stein EM, DiNardo CD, Pollyea DA, et al. Enasidenib in mutant IDH2 relapsed or refractory acute myeloid leukemia. *Blood* 2017;130:722-731. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/28588020>.
6. 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.

7. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 20, 2022.
8. Acute Myeloid Leukemia. V2.2022. Revised June 14, 2022.

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.

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