

# 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) (Label, NCCN 2A);

### **OR**

- III. Individual has a diagnosis of acute myeloid leukemia (AML); **AND**
- IV. Individual has an isocitrate dehydrogenase-2 (IDH2) mutation (Label, NCCN 2A); **AND**
- V. Individual meets one of the following:
  - A. Individual is using as treatment induction therapy and cannot use intensive remission induction therapy; **OR**
  - B. Individual is using as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen; **OR**
  - C. Individual is using as consolidation therapy as continuation of low-intensity regimen used for induction therapy.

### Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. 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>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; 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™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 3, 2025.
8. Acute Myeloid Leukemia. V2.2025. Revised January 27, 2025.

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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