Reference number(s)
2238-A

Specialty Guideline Management
Idhifa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Idhifa	enasidenib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication[1]

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

Compendial Uses[2]

- IDH2-mutated AML
- Myelodysplatic Syndromes (MDS)

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
2238-A

Documentation

Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of isocitrate dehydrogenase-2 (IDH2) mutation

Coverage Criteria

Acute Myeloid Leukemia (AML)[1-2]

Authorization of 12 months may be granted for induction treatment of newly diagnosed AML with a susceptible IDH2 mutation when all of the following criteria is met:

- The requested medication will be used as a single agent or in combination with azacitidine
- Member is not a candidate for or declines intensive induction therapy

Authorization of 12 months may be granted for post-induction therapy for AML with a susceptible IDH2 mutation when all of the following criteria is met:

- The requested medication will be used as a single agent or in combination with azacitidine
- Member has experienced response to Idhifa therapy

Authorization of 12 months may be granted for treatment as a single agent of relapsed or refractory AML with a susceptible IDH2 mutation.

Myelodysplastic Syndromes (MDS)[2]

Authorization of 12 months may be granted for subsequent treatment of MDS in members with a susceptible IDH2 mutation.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Coverage Criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Idhifa [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; January 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 23, 2025.