

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Idhifa Prior Authorization Policy

- Idhifa® (enasidenib tablets – Celgene/Servier/Bristol-Myers Squibb)

**REVIEW DATE:** 02/23/2022

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### OVERVIEW

Idhifa, an isocitrate dehydrogenase-2 (*IDH2*) inhibitor, is indicated for the treatment of relapsed or refractory **acute myeloid leukemia** in adults with an *IDH2* mutation as detected by an FDA-approved test.<sup>1</sup>

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on acute myeloid leukemia (version 1.2022 – December 2, 2021) note Idhifa as an alternative for *IDH2* mutated AML in a variety of clinical scenarios. Idhifa is recommended for patients who have relapsed or refractory disease who have the *IDH2* mutation. Another clinical scenario is for treatment induction among patients  $\geq 60$  years of age who are not a candidate for intensive remission induction therapy or declines such therapy. In patients  $\geq 60$  years of age who had a response to previous lower intensity therapy, Idhifa can be continued. Both clinical scenarios apply to patients who are *IDH2* mutation positive.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Idhifa. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Idhifa is recommended in those who meet the following criteria:

#### FDA-Approved Indication

1. **Acute Myeloid Leukemia (AML).** Approve for 3 years if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has isocitrate dehydrogenase-2 (*IDH2*)-mutation positive disease as detected by an approved test.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Idhifa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Idhifa® tablets [prescribing information]. Summit, NJ: Celgene; November 2020.
  2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – December 2, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 16, 2022.
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