PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Idhifa Prior Authorization Policy
- Idhifa® (enasidenib tablets – Celgene/Servier/Bristol-Myers Squibb)

REVIEW DATE: 03/12/2025

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.[1]

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on acute myeloid leukemia (version 2.2025 – January 27, 2025) recommend Idhifa for *IDH2* mutated AML in a variety of clinical scenarios, such as treatment induction, follow-up after induction therapy, consolidation therapy, or relapsed or refractory disease (category 2A).

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.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 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/Bristol Myers Squibb; January 2025.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – January 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 10, 2025.