UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1228-7
Program	Prior Authorization/Notification
Medication	Idhifa® (enasidenib)
P&T Approval Date	9/1/2017, 9/2018, 9/2019, 9/2020, 9/2021, 9/2022, 9/2023
Effective Date	12/1/2023

1. Background:

Idhifa® (enasidenib) is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test. The National Cancer Comprehensive Network (NCCN) also recommends the use of Idhifa as a single agent, or in combination with azacitidine, in patients with IDH2-mutated AML for treatment induction when not a candidate for intensive induction therapy, as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen, or as consolidation therapy as continuation of low-intensity regimen used for induction.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. Patients less than 19 years of age

1. **Idhifa** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. Acute Myeloid Leukemia (AML)

1. **Initial Authorization**

   a. **Idhifa** will be approved based on **all** of the following criteria:

   (1) Diagnosis of acute myeloid leukemia (AML)

   -AND-

   (2) AML is IDH2 mutation-positive

   -AND-

(3) **One** of the following:

(a) Disease is relapsed or refractory

-OR-

(b) Used as low-intensity treatment induction when not a candidate for intensive induction therapy

-OR-

(c) Used for consolidation therapy as continuation of low-intensity regimen used for induction

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Idhifa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Idhifa therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Idhifa [package insert]. Cambridge, MA: Celgene Corporation; August 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed July 31, 2023.

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Change Control	
9/2017	New program.
9/2018	Annual review. Updated background and criteria to include off label NCCN recommended utilization. Updated reference.
9/2019	Annual review with no changes to clinical coverage criteria. Updated reference. Added general NCCN recommended review criteria.
9/2020	Annual review with no changes to clinical coverage criteria. Updated reference.
9/2021	Annual review with no changes to coverage criteria. References updated.
9/2022	Annual review. Updated criteria based on latest NCCN recommendations. Updated reference.
9/2023	Annual review. Updated criteria based on latest NCCN recommendations. Updated reference.