UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Idhifa

Program	Prior Authorization
Medication	Idhifa® (enasidenib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2017
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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 for patients 60 years of age or older with IDH2 mutated AML who are not candidates for intensive induction therapy or for post remission therapy following response to lower intensity induction therapy.

Idhifa has a black box warning for differentiation syndrome with or without concomitant hyperleukocytosis. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. <u>Acute Myeloid Leukemia (AML)</u>

1. <u>Initial Authorization</u>

a. **Idhifa** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of acute myeloid leukemia (AML)

-AND-

(2) AML is IDH2 mutation-positive

-AND-

(3) **<u>One</u>** of the following:

(a) Disease is relapsed or refractory

-OR-

(b) **Both** of the following:

i. Patient is 60 years of age or older

-AND-

ii. **One** of the following:

1. Patient is not a candidate for intensive induction therapy

-OR-

2. Used for post remission therapy following response to low intensity induction therapy

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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Idhifa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Idhifa therapy **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; September 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. AccessedAugust 6, 2020.

Program	Prior Authorization –Idhifa (enasidenib)
Change Control	
Date	Change
9/2017	New program
9/2018	Updated background and criteria to include NCCN recommended utilization. Updated references.
9/2019	Annual review. Updated references.
9/2020	Annual review. Updated references. Added Additional Clinical Rules section.