Reference number(s)
2238-A

SPECIALTY GUIDELINE MANAGEMENT

IDHIFA (enasidenib)

POLICY

I. 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.

A. FDA-Approved Indication
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.

B. Compendial Uses
As a single agent in patients 60 years of age or older with IDH2-mutated AML in the following settings:
1. Treatment induction when not a candidate for intensive remission induction therapy or declines intensive therapy
2. Post-induction therapy following response to previous lower intensity therapy with the same regimen

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

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia (AML)

A. Authorization of 12 months may be granted for treatment induction of newly diagnosed AML with a susceptible IDH2 mutation when all of the following criteria is met:
1. The requested medication will be used as a single-agent
2. Member is age 60 years or older
3. Member has comorbidities that preclude the use of intensive induction chemotherapy or declines intensive induction chemotherapy

B. 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:
1. The requested medication will be used as a single-agent
2. Member is age 60 years or older
3. Member has experienced response to Idhifa therapy.

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

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Idhifa [package insert]. Summit, NJ: Celgene Corporation; November 2020.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 7, 2022.