Dear NCCN Acute Myeloid Leukemia Guidelines Panel:

On behalf of Celgene Corporation, we respectfully request that the NCCN Guidelines Panel for Acute Myeloid Leukemia (AML) review the enclosed information regarding the importance of isocitrate dehydrogenase-2 (IDH-2) testing for AML patients. Please also reference the IDHIFA® (enasidenib) submission made by Celgene Corporation on August 2, 2017 and the IDH testing submission made by Celgene Corporation on July 14, 2016.

Specific Change:
Include a recommendation to test patients for an IDH-2 mutation as it may assist in identifying appropriate treatment options, including recently approved IDH-2 inhibitor, IDHIFA.

FDA Status: On August 1, 2017, IDHIFA was approved for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with an IDH-2 mutation as detected by an FDA-approved test.¹

Please note Boxed WARNING for Differentiation Syndrome: Patients treated with IDHIFA have experienced symptoms of differentiation syndrome, which can be fatal if not treated. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

Rationale for Proposed Addition:
As stated in the current NCCN Guidelines for AML, Version 3.2017, the evaluation of several molecular markers may be important for risk assessment and prognostication, and may also guide treatment decisions (MS-3). The recently published College of American Pathologists (CAP) – American Society of Hematology (ASH) – Initial Diagnostic Workup of Acute Leukemia Guidelines includes a recommendation for mutational analysis, including testing for IDH-2 mutation for prognostic and/or therapeutic purposes.² In addition, the 2016 Revision to the World Health Organization (WHO) Classification of Myeloid Neoplasms and Acute Leukemia includes IDH1 and IDH2 into the supplemental table for molecular genetic alterations affecting clinical outcome of AML patients in specific cytogenetic groups.³⁴

Your consideration of this submission is greatly appreciated.
Reference List


Sincerely,

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