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Date of Request: May 16, 2019
NCCN Guideline Panel: Hepatobiliary Cancer

On behalf of Eli Lilly and Company, I respectfully request the NCCN Hepatobiliary Cancer Panel to review the attached updated label for CYRAMZA® (ramucirumab).

Specific changes requested:
The purpose of this letter is to inform you of updated prescribing information for ramucirumab. No changes are requested at this time.

FDA Clearance:
On May 10, 2019, ramucirumab was approved for use as a single agent for the treatment of patients with hepatocellular carcinoma (HCC) who have an alpha fetoprotein (AFP) of ≥400 ng/mL and have been treated with sorafenib.[1]

This approval was based on clinical evidence from the REACH-2 clinical trial, a global, randomized, double-blind, placebo-controlled phase 3 study in which patients with HCC and AFP ≥400 ng/mL received either ramucirumab 8 mg/kg or placebo intravenously every two weeks.[2]

Concurrent with this approval, the FDA has also removed the Boxed Warning from the ramucirumab labeling which highlighted warnings pertaining to hemorrhage, gastrointestinal perforation, and impaired wound healing.[1] The updated ramucirumab labeling continues to provide important information on these specific risks, as well as other risks and adverse events.

Please refer to the product prescribing information for the full FDA-approved indications and safety information.[1]

References
The following references are submitted to assist the committee in their review:

1. CYRAMZA® (ramucirumab) Prescribing Information
2. Zhu AX, Kang YK, Yen CJ, et al. Ramucirumab after sorafenib in patients with advanced hepatocellular carcinoma and increased α-fetoprotein concentrations (REACH-2): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Oncol. 2019;20(2):282-296. http://dx.doi.org/10.1016/S1470-2045(18)30937-9.

Sincerely,

Jessie L. Fahrbach, MD
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