

From: [William G. Losin](#)
To: [Submissions](#)
Subject: Cyramza - Now approved in the US for the treatment of colorectal cancer
Date: Tuesday, April 28, 2015 11:21:52 AM
Attachments: [image001.png](#)
[Cyramza-USPI_24_April_2015.pdf](#)
[sBLA_125477-11 Approval Letter and PI.PDF](#)

On behalf of Lilly Oncology, please see the attached updated prescribing information for CYRAMZA® (ramucirumab) injection, for intravenous use, for review by your editorial board.

On April 24, 2015, CYRAMZA® was approved by the Food and Drug Administration (FDA) for use in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) for the treatment of patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.

CYRAMZA® has been previously approved by the FDA for the following indications:

- **Gastric Cancer:** as a single agent, or in combination with paclitaxel, for the treatment of patients with advanced or metastatic, gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy.
- **Non-Small Cell Lung Cancer:** in combination with docetaxel, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy.

See important safety information, including the Boxed Warning for hemorrhage, gastrointestinal perforation, and impaired wound healing, in the accompanying full prescribing information.

WARNING: HEMORRHAGE, GASTROINTESTINAL PERFORATION, AND IMPAIRED WOUND HEALING

See full prescribing information for complete boxed warning.

- Hemorrhage: CYRAMZA increased the risk of hemorrhage, and gastrointestinal hemorrhage, including severe and sometimes fatal hemorrhagic events. Permanently discontinue CYRAMZA in patients who experience severe bleeding. (2.3, 5.1)
- Gastrointestinal Perforation: Permanently discontinue CYRAMZA in patients who experience a gastrointestinal perforation. (2.3, 5.5)
- Impaired Wound Healing: Withhold CYRAMZA prior to surgery and discontinue CYRAMZA if a patient develops wound healing complications (2.3, 5.6)

Included are the following attachments:

- Prescribing Information
- FDA approval letter

For information regarding pricing, please contact Lynsey Sell at (317) 277-7085 or sell_lynsey@lilly.com.

For medical inquiries, please contact me directly.

Sincerely,

William G. Losin, Pharm.D.
Consultant, Oncology Medical Information
Eli Lilly & Company
Lilly Corporate Center
Indianapolis, IN 46285
(317) 433-1519
losin_william_g@lilly.com