Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Cyramza (ramucirumab)

DRUG.00067

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Cyramza (ramucirumab)

APPROVAL CRITERIA

Requests for Cyramza (ramucirumab) may be approved if the following are met:

I. Individual has a diagnosis of advanced (non-resectable) or metastatic esophageal, gastric, or gastro-esophageal junction adenocarcinoma with disease progression that occurs during or after fluoropyrimidine- or platinum-containing chemotherapy; **AND**
   A. Individual is using as a single-agent or in combination with paclitaxel;

OR

II. Individual is using in combination with docetaxel for the treatment of metastatic non-small cell lung cancer (NSCLC) when either of the following criteria is met:
   A. Individual does not have an epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor mutation, and the disease has progressed on or after platinum-containing chemotherapy;

   OR
   B. Individual has an EGFR or ALK genomic tumor mutation and both of the following criteria are met:
      1. Disease has progressed on a U.S. Food & Drug Administration (FDA)-approved therapy (for example; afatinib, crizotinib, erlotinib, or gefitinib) for these mutations prior to receiving ramucirumab; **AND**
      2. Disease has progressed on or after platinum-containing chemotherapy;

OR

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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III. Individual has a diagnosis of metastatic colorectal cancer (mCRC) with disease progression that occurs during or after bevacizumab-, oxaliplatin-, and fluoropyrimidine-containing chemotherapy; **AND**
   A. Individual is using in combination with irinotecan, folinic acid, and 5-fluorouracil (FOLFIRI);

OR

IV. Individual is using with docetaxel for the treatment of locally advanced, unresectable or metastatic urothelial cancer originating from the bladder, urethra, ureter, or renal pelvis; **AND**
   A. Individual is 18 years of age or older; **AND**
   B. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
   C. Disease has progressed after platinum-containing chemotherapy (cisplatin or carboplatin); **AND**
   D. Individual has received treatment with no more than one immune checkpoint inhibitor (such as, atezolizumab, avelumab, durvalumab, nivolumab or pembrolizumab); **AND**
   E. Individual has received treatment with no more than one prior systemic chemotherapy regimen in the relapsed or metastatic setting; **AND**
   F. Individual has received no prior systemic taxane therapy in any setting (that is, neoadjuvant, adjuvant, or metastatic).

Cyramza (ramucirumab) may **not** be approved when the criteria above are not met and for all other indications, including but not limited to:

1. Breast cancer
2. Hepatocellular cancer
3. Metastatic melanoma
4. Ovarian, fallopian tube or primary peritoneal cancer
5. Renal cell cancer

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Note: Cyramza (ramucirumab) has a black box warning for hemorrhage, gastrointestinal perforation, and impaired wound healing:

- 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.
- Gastrointestinal Perforation: Permanently discontinue Cyramza in patients who experience a gastrointestinal perforation.
- Impaired Wound Healing: Withhold Cyramza prior to surgery and discontinue Cyramza if a patient develops wound healing complications.

State Specific Mandates		
State	Date effective	Mandate details (including specific bill if applicable)
N/A	NA	NA

Key References:

1. Cyramza [Product Information]. Indianapolis, IN. Eli Lilly and Company; March 2017. Available at: http://pi.lilly.com/us/cyramza-pi.pdf. Accessed on June 11, 2018.
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3. Janmaat VT, Steyerberg EW, van der Gaast A, et al. Palliative chemotherapy and targeted therapies for esophageal and gastroesophageal junction cancer. Cochrane Database Syst Rev. 2017;(11):CD004063.
4. National Comprehensive Cancer Network®. NCCN® Drugs & Biologic Compendium® (electronic version). For additional information visit the NCCN website: http://www.nccn.org. Accessed on June 11, 2018.
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   - Bladder Cancer (V4.2018). Revised May 22, 2018.
   - Colon Cancer (V2.2018). Revised March 14, 2018.
   - Esophageal and Esophagogastric Junction Cancers (V2.2018). Revised May 22, 2018.
   - Gastric Cancer (V2.2018). Revised May 22, 2018.
   - Non-Small Cell Lung Cancer (V4.2018). Revised April 26, 2018.
   - Rectal Cancer (V1.2018). Revised March 14, 2018.
6. Ramucirumab. In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Last updated February 2, 2018. Available at: http://www.micromedexsolutions.com. Accessed on June 11, 2018.
7. U.S. National Institutes of Health (NIH). ClinicalTrials.gov. Search: ramucirumab. Available at: https://www.clinicaltrials.gov/ct2/results?term=ramucirumab&Search=Search. Accessed on June 11, 2018.
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