Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Cyramza (ramucirumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Cyramza (ramucirumab)

APPROVAL CRITERIA

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

I. Individual has a diagnosis of Hepatocellular Carcinoma and the following are met:
   A. Individual has inoperable or metastatic disease (NCCN 2A); **AND**
   B. Individual has had disease progression on or after prior treatment with Sorafenib; **AND**
   C. Ramucirumab is used as a single agent; **AND**
   D. Individual has a baseline serum α–fetoprotein (AFP) concentrations of ≥ 400 ng/mL at initiation of therapy;

OR

II. Individual has a diagnosis of Esophageal, Gastric, or Gastro-esophageal Junction Adenocarcinoma and the following criteria are met:
   A. Individual has advanced (non-resectable) or metastatic disease ; **AND**
   B. Ramucirumab is used as a single-agent or in combination with paclitaxel; **AND**
   C. Individual has had progression that occurs on or after fluoropyrimidine- or platinum-containing chemotherapy;

OR

III. Individual has a diagnosis of metastatic Non-small Cell Lung Cancer (NSCLC) and the following are met:
   A. Ramucirumab is used in combination with docetaxel; **AND**
   B. Individual meets either of the following:
      1. 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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

2. Individual has an EGFR or ALK genomic tumor mutation and both of the following criteria are met:
    a. 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**
    b. Disease has progressed on or after platinum-containing chemotherapy;

OR

IV. Individual has a diagnosis of metastatic Non-small Cell Lung Cancer (NSCLC) and the following are met:
    A. Individual has an EGFR exon 19 deletion or exon 21 (L858R) substitution mutation with test results confirmed; **AND**
    B. Ramucirumab is used as first line therapy in combination with erlotinib (NCCN 2A);

OR

V. Individual has a diagnosis of metastatic Colorectal Cancer (mCRC) and the following are met:
    A. Individual has had disease progression on or after prior bevacizumab-, oxaliplatin-, and fluoropyrimidine- containing chemotherapy; **AND**
    B. Ramucirumab is used in combination with irinotecan, folinic acid, and 5-fluorouracil (FOLFIRI);

OR

VI. Individual has a diagnosis of Urothelial Cancer originating from the bladder, urethra, ureter, or renal pelvis and the following are met (Petrylak 2017):
    A. Individual is 18 years of age or older; **AND**
    B. Ramucirumab is used in combination with docetaxel; **AND**
    C. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
    D. Individual has locally advanced, unresectable, or metastatic disease that has progressed after platinum-containing chemotherapy (cisplatin or carboplatin); **AND**
    E. Individual has received treatment with no more than one immune checkpoint inhibitor (such as, atezolizumab, avelumab, durvalumab, nivolumab or pembrolizumab); **AND**
    F. Individual has received treatment with no more than one prior systemic chemotherapy regimen in the relapsed or metastatic setting; **AND**
    G. Individual has received no prior systemic taxane therapy in any setting (that is, neoadjuvant, adjuvant, or metastatic).

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Requests for Cyramza (ramucirumab) may **not** be approved for the following:

I. Ramucirumab is used for colorectal cancer in combination with the same irinotecan-based regimen that was previously used in combination with bevacizumab (or bevacizumab biosimilar); **OR**

II. All other indications not listed above; including but not limited to:
   A. Breast cancer; **OR**
   B. Metastatic melanoma; **OR**
   C. Ovarian, fallopian tube or primary peritoneal cancer; **OR**
   D. Renal cell cancer.

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   a. Esophageal and Esophagogastric Junction Cancers. V4.2019. Revised December 20, 2019.
   b. Non-Small Cell Lung Cancer. V2.2020. Revised December 23, 2019.
   c. Colon Cancer. V1.2020. Revised December 19, 2019.
   d. Hepatobiliary Cancers. V4.2019. Revised December 20, 2019.
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