Cyramza® (ramucirumab)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Indication	Billable Units (BU)	Per unit time (days)
Gastric/Esophageal/Esophagogastric Junction/Gastroesophageal Junction Cancers, CRC, Appendiceal Adenocarcinoma, & HCC	180 BU	14 days
NSCLC	240 BU	14 days
PM, Thymic Carcinoma	240 BU	21 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient does not have uncontrolled severe hypertension; **AND**
- Patient must not have had a surgical procedure within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**

Colorectal Cancer (CRC) ¥ † ‡ [1,3,9-11,17,18]

- Used in combination with irinotecan or FOLFIRI (irinotecan, folinic acid/leucovorin, and fluorouracil); **AND**
  - Used as initial treatment for unresectable metastatic disease after previous FOLFOX (fluorouracil, folinic acid/leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months ‡; **OR**
  - Used as subsequent therapy for progression of advanced or metastatic disease; **AND**

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- Patient has not previously been treated with irinotecan-based therapy

¥ *Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed patients. If deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB>50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the patient is a candidate.*

Appendiceal Adenocarcinoma – Colon Cancer ¥ ‡ [3]

- Used as subsequent therapy in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan) for progression of advanced or metastatic disease; **AND**
- Patient has not previously been treated with irinotecan-based therapy or with oxaliplatin

¥ *Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed patients. If deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB>50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the patient is a candidate.*

Gastric, Esophageal, and Esophagogastric/Gastroesophageal Junction Cancers † ‡ Φ [1-3,5-7,14,15]

- Patient has adenocarcinoma histology; **AND**
- Used as subsequent therapy; **AND**
- Used as a single agent OR in combination with paclitaxel OR in combination with an irinotecan-based regimen; **AND**
  - Patient has advanced, recurrent, or metastatic disease; **OR**
  - Patient is not a surgical candidate

Hepatocellular Carcinoma (HCC) † ‡ Φ [1,3,4,16]

- Used as a single agent; **AND**
- Used as subsequent therapy for progressive disease; **AND**
- Patient has an alfa-fetoprotein (AFP) level of ≥ 400 ng/mL; **AND**
- Patient has Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments)

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,3,8,12,13]

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used in combination with docetaxel; **AND**
    - Used as subsequent therapy for first progression after initial systemic therapy; **AND**
    - Patient has not previously been treated with docetaxel or ramucirumab; **OR**
  - Used in combination with erlotinib; **AND**

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- Patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**
  - ➢ Used as first-line therapy; **OR**
  - ➢ Used for continuation of therapy following disease progression on combination erlotinib and ramucirumab therapy for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited progression; **AND**
    - – Patient has T790M negative disease

Pleural Mesothelioma (PM)* ‡ [3,19,20]

- Used in combination with gemcitabine as subsequent therapy

**Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

Thymic Carcinoma ‡ [3,21,22]

- Used in combination with carboplatin and paclitaxel^; **AND**
  - Used as preoperative therapy for surgically resectable disease if R0 resection is considered uncertain; **OR**
  - Used as postoperative therapy after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; **OR**
  - Used as first-line therapy for recurrent, advanced, or metastatic disease

^Ramucirumab may be continued as maintenance monotherapy

❖ *If confirmed using an immunotherapy assay – http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1,3,13]

Prior authorization validity may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread, unless otherwise specified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hemorrhage, arterial thromboembolic events, uncontrolled hypertension, infusion-related reactions, severe proteinuria (> 3g/24h), nephrotic syndrome, gastrointestinal perforations, impaired wound healing, posterior reversible encephalopathy syndrome (PRES), thyroid dysfunction, worsening of pre-existing hepatic impairment, etc.

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V. Dosage/Administration [1,13-15,17,18,20-22]

Indication	Dose
CRC, Appendiceal Adenocarcinoma, Gastric/Esophageal/ Esophagogastric/Gastroesophageal Junction Cancers, HCC	Administer 8 mg/kg intravenously every 14 days until disease progression or unacceptable toxicity
NSCLC	In combination with docetaxel: Administer 10 mg/kg intravenously every 21 days until disease progression or unacceptable toxicity In combination with erlotinib: Administer 10 mg/kg intravenously every 14 days until disease progression or unacceptable toxicity
Pleural Mesothelioma	In combination with gemcitabine: Administer 10 mg/kg intravenously every 21 days until tumor progression or unacceptable toxicity
Thymic Carcinoma	Administer 10 mg/kg intravenously every 21 days until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J9308 − Injection, ramucirumab, 5 mg; 1 billable unit = 5 mg

NDC(s):

- Cyramza 100 mg/10 mL solution, single-dose vial: 00002-7669-xx
- Cyramza 500 mg/50 mL solution, single-dose vial: 00002-7678-xx

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach

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ICD-10	ICD-10 Description
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of large intestines
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung

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ICD-10	ICD-10 Description
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C37	Malignant neoplasm of thymus
C45.0	Mesothelioma of pleura
C45.2	Mesothelioma of pericardium
C45.7	Mesothelioma of other sites
C45.9	Mesothelioma, unspecified
C78.00	Secondary malignant neoplasm of lung
C78.01	Secondary malignant neoplasm of lung
C78.02	Secondary malignant neoplasm of lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
D15.0	Benign neoplasm of thymus
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.4	Neoplasm of uncertain behavior of thymus
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of malignant neoplasm of large intestine
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.238	Personal history of other malignant neoplasm of thymus

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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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