Cyramza (ramucirumab)

Line(s) of Business: HMO; PPO; QUEST Integration Medicare Advantage

Original Effective Date: 10/01/2015

Current Effective Date: 03/01/2018

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

**Gastric Cancer**
Cyramza as a single agent, or in combination with paclitaxel, is indicated for the treatment of patients with advanced or metastatic, gastric or gastro-esophageal junction (GEJ) adenocarcinoma with disease progression on or after prior fluoropyrimidine-or platinum-containing chemotherapy.

**Non-Small Cell Lung Cancer (NSCLC)**
Cyramza, in combination with docetaxel, is indicated for the treatment of patients with metastatic NSCLC with disease progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza.

**Colorectal Cancer**
Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) is indicated for the treatment of patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.

Compendial Uses

**Esophageal and Esophagogastric Junction Cancers**
Cyramza is recommended as palliative therapy for patients with Karnofsky performance score ≥60% or ECOG performance score ≤2 as a single agent or in combination with paclitaxel as preferred second-line therapy for unresectable locally advanced, recurrent, or metastatic esophageal or esophagogastric junction (EGJ) adenocarcinoma.

**Gastric Cancer**
Cyramza is recommended as palliative therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease and Karnofsky performance score ≥60% or ECOG performance score ≤2 as a single agent or in combination with paclitaxel as preferred second-line therapy.
Non-Small Cell Lung Cancer (NSCLC)
Cyramza is recommended as subsequent therapy in combination with docetaxel for metastatic disease following progression on a cytotoxic regimen for patients with performance status 0-2 who have not previously received docetaxel.

Colorectal Cancer
Cyramza, in combination with irinotecan or FOLFIRI (irinotecan, folic acid, and 5-fluorouracil) is recommended for:
- Primary treatment for patients with unresectable metachronous metastases and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months
- Subsequent therapy after first progression for unresectable advanced or metastatic disease not previously treated with an irinotecan-based regimen

B. REQUIRED DOCUMENTATION
The following documentation from the medical record is necessary to initiate the prior authorization review:
- For all indications: Current oncology notes and treatment plan, clinical notes that include the history of previous treatments, and any pertinent pathology reports and/or imaging studies
- NSCLC: ALK and EGFR mutation statuses and previous targeted therapy (if applicable)

C. PRESCRIBER RESTRICTION
Prescriber must be an oncologist.

D. CRITERIA FOR APPROVAL
Cyramza will be discontinued if severe bleeding occurs.

1. Gastric/Gastro-esophageal junction (GEJ) adenocarcinoma
   Authorization of 3 months may be granted to members who are prescribed Cyramza when ALL of the following criteria are met:
   a. Member has unresectable locally advanced, recurrent or metastatic disease or is not a surgical candidate
   b. Member has experienced disease progression on or after ANY of the following:
      i. Fluoropyrimidine-containing regimen
      ii. Platinum-containing regimen
   c. Cyramza will be used either as a single agent (monotherapy) OR in combination with paclitaxel

2. NSCLC
   Authorization of 6 months may be granted to members who are prescribed Cyramza when ALL of the following criteria are met:
   a. Member has metastatic disease
   b. Member has experienced disease progression on or after a cytotoxic chemotherapy regimen
   c. Cyramza will be used in combination with docetaxel
   d. For members with ALK positive mutations, member has experienced disease progression on an ALK inhibitor (eg, crizotinib [Xalkori], ceritinib [Zykadia]).
e. For members with EGFR positive mutations, member has experienced disease progression on an EGFR tyrosine kinase inhibitor (eg, erlotinib [Tarceva], afatinib [Gilotrif], gefitinib [Iressa]).

3. Colorectal Cancer
Authorization of 6 months may be granted to members who are prescribed Cyramza as primary treatment for unresectable metachronous metastases when the following criteria are met:
   a. Cyramza is used in combination with irinotecan or with FOLFIRI (fluorouracil, leucovorin, and irinotecan)
   b. Member has previously received adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

Authorization of 6 months may be granted to members who are prescribed Cyramza as therapy after first progression for unresectable advanced or metastatic disease when the following criteria are met:
   a. Cyramza is used in combination with irinotecan or with FOLFIRI (fluorouracil, leucovorin, and irinotecan)
   b. Member has not previously received an irinotecan-based regimen.

E. CONTINUATION OF THERAPY
1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.
2. Reauthorization:
   a. Gastric/Gastro-esophageal junction (GEJ) adenocarcinoma
      Members who were previously approved for Cyramza by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 3 months may be granted if the following information is supplied:
      - A current oncology note documenting the patient’s response to treatment showing no progression of disease
      - Current imaging studies and other objective measures showing no progression of disease when compared with previous results
   b. NSCLC
      Members who were previously approved for Cyramza by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 6 months may be granted if the following information is supplied:
      - A current oncology note documenting the patient’s response to treatment showing no progression of disease
      - Current imaging studies and other objective measures showing no progression of disease when compared with previous results
   c. Colorectal Cancer
      Members who were previously approved for Cyramza by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 6 months may be granted if the following information is supplied:
      - A current oncology note documenting the patient’s response to treatment showing no progression of disease
      - Current imaging studies and other objective measures showing no progression of disease when compared with previous results
F. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

Document History

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