

**Policy: MBP 115.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Cyramza (ramucirumab)**

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**I. Policy:**

Cyramza (ramucirumab)

**II. Purpose/Objective:**

To provide a policy of coverage regarding Cyramza (ramucirumab)

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

**Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

**DESCRIPTION:**

Cyramza (ramucirumab) is a vascular endothelial growth factor receptor 2 (VEGFR2) antagonist that specifically binds VEGF Receptor 2 and blocks binding of VEGFR ligands.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

**GRANDFATHER PROVISION** – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Cyramza (ramucirumab) will be considered medically necessary for all lines of business when all of the following criteria are met:

**1. Advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma:**

- Prescription is written by an oncologist **AND**
- Medical record documentation of:
  - Advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine or platinum containing chemotherapy **AND**
  - Medical record documentation of use in combination with paclitaxel **OR** for use as monotherapy

**2. NSCLC:**

- Prescription is written by an oncologist **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations **AND**
  - Medical record documentation that Cyramza will be used as first-line treatment in combination with erlotinib**OR**
  - Medical record documentation of metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy **AND**
  - Patients with EGFR or ALK genomic tumor aberrations must provide medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza **AND**
  - Medical record documentation of use in combination with docetaxel

**3. Metastatic Colon or Rectal Cancer:**

- Prescription is written by an oncologist **AND**
- Medical record documentation of metastatic colon or rectal cancer with disease progression on or after FOLFOX, CapeOX or a regimen not previously containing irinotecan **AND**
- Medical record documentation of use in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan)

**4. Hepatocellular Carcinoma (HCC):**

- Prescription is written by an oncologist **AND**
- Medical record documentation of a diagnosis of hepatocellular carcinoma **AND**
- Medical record documentation of an alpha fetoprotein (AFP) level of  $\geq 400\text{ng/mL}$  **AND**
- Medical record documentation of disease progression on or after treatment with sorafenib (Nexavar) or an intolerance to sorafenib (Nexavar)

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

**LINE OF BUSINESS:**

**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

**REFERENCES:**

1. Cyramza [prescribing information]. Indianapolis, IN: Eli Lilly and Company; June 2021.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 7/15/14

**Revised:** 1/20/15 (added additional GA cancer criteria and new indication) 3/24/15 (auth duration), 7/21/15 (new indication), 6/29/16 (updated GA cancer criteria), 3/28/19 (grandfather), 7/16/19 (HCC, gastro update), 8/27/20 (NSCLC, first line), 6/23/22 (Medicaid PARP statement), 6/6/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added)

**Reviewed:** 5/27/16, 5/16/17, 5/1/18, 7/1/20, 7/26/21, 5/29/24

**MA UM Committee approval:** 12/31/23