OncoHealth

Cyramza (Ramucirumab)

Effective Date: 9/1/20
Revision Date(s): 7/22, 11/22, 12/22, 7/23, 4/24
Review Date: 4/5/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Universal Criteria

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.; **AND**
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Indication Specific Criteria

Hepatocellular Carcinoma

- The member has unresectable, locally advanced, or metastatic disease; **AND**
- Cyramza is used as subsequent therapy; **AND**
- Cyramza is used as a single agent; **AND**
- The member's liver functional status is Child-Pugh Class A[1]; **AND**
- The member's AFP (alpha-fetoprotein) is ≥400 ng/mL

Non-Small Cell Lung Cancer

- Member has recurrent, advanced, or metastatic disease; AND
    - Cyramza is used in combination with docetaxel; **AND**
        - Used as subsequent therapy; **AND**
        - Member has an ECOG of 0-2[2]; **OR**
    - Cyramza is used in combination with erlotinib; **AND**
        - Member has EGFR exon 19 deletion or exon 21 (L858R) mutation; **AND**
        - Used as first-line therapy; **OR**

[1] Child-Pugh Class B will be considered on a case-by-case basis
[2] ECOG score of greater than 2 will be considered on a case-by-case basis.

- Used as continuation of therapy following disease progression on erlotinib and ramucirumab IF:
  - Member has asymptomatic disease; **OR**
  - Member has symptomatic brain lesions; **OR**
  - Member has symptomatic systemic limited metastases and T790M mutation negative; **OR**
- Cyramza is used in combination with pembrolizumab[10]; **AND**
  - Used in the subsequent-line setting; **AND**
  - Member received prior therapy with a PD-1/PD-L1 inhibitor given sequentially or in combination with a platinum doublet chemotherapy regimen; **AND**
  - Member experienced disease progression at least 84 days after initiation of first-line therapy with a PD-1/PD-L1 inhibitor in combination with a platinum doublet chemotherapy regimen

Universal Approval Criteria

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
  - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
  - Clinical Pharmacology (Strong For)
  - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
  - Thompson Micromedex DrugDex® (Class I and IIa)
  - Wolters Kluwer Lexi-Drugs® (Level A)
- Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
  - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
  - **Meeting abstracts and case reports are excluded from consideration.**
- Non-standard protocols may be approved based on unique clinical circumstances.

Billing

Drug Name	HCPCS Code	Description
Cyramza	J9308	Inj., ramucirumab, 5 mg

References

1. Cyramza [package insert]. Eli Lilly and Company, Indianapolis, IN. Available at: https://uspl.lilly.com/cyramza/cyramza.html#pi
2. Cyramza. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 5th 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.
4. Reckamp KL, et al. Phase II Randomized Study of Ramucirumab and Pembrolizumab Versus Standard of Care in Advanced Non-Small-Cell Lung Cancer Previously Treated with Immunotherapy – Lung-MAP S1800A. JCO 2022;40: 2295-2306

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Date	Updates
11/7/22	Policy approved by P&T
12/12/22	Updated formatting and incorporated universal criteria
7/19/23	Updated Hepatocellular Indication Specific Criteria (from Hepatobiliary). Added Approval Criteria. Added Mesothelioma: Pleural NCCN Guidelines to References.
4/5/24	Annual Review. Updated Universal Criteria. Updated references.