OncoHealth

Cyramza (Ramucirumab)

Effective Date: 9/1/20
Revision Date(s): 7/22, 11/22, 12/22, 7/23
Review Date: 7/19/2023
Policy type: Medical Necessity

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

Universal Criteria Applied to All Requests

- Indication specific criteria should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature, unless documented below.
- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

Indication Specific Criteria

Hepatocellular Carcinoma

- Member has unresectable, locally advanced, or metastatic disease; AND
- Used as subsequent therapy; AND
- Used as a single agent; AND
- Member's liver functional status is Child-Pugh Class A; AND
    - Child-Pugh Class B may be considered for some patients based on their clinical presentation.
- Member's AFP (alpha-fetoprotein) ≥400 ng/mL

Non-Small Cell Lung Cancer

- Member has recurrent, advanced, or metastatic disease; AND
    - Used in combination with docetaxel; AND
        - Used as subsequent therapy; OR
    - Used in combination with erlotinib; AND
        - Member has EGFR exon 19 deletion or exon 21 (L858R) mutation; AND
        - Used as first-line therapy; OR
        - 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
    - Used in combination with pembrolizumab[10]; AND
        - Used in the subsequent-line setting; AND

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- Member received prior therapy with a PD-1/PD-L1 inhibitor in combination with a platinum doublet chemotherapy regimen; AND
- Member experienced disease progression at least 84 days after first-line therapy with a PD-1/PD-L1 inhibitor in combination with a platinum doublet chemotherapy regimen

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. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 7/19/23
2. Cyramza [package insert]. Eli Lilly and Company, Indianapolis, IN. Available at: https://uspl.lilly.com/cyramza/cyramza.html#pi

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3. Colon Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed 7/19/23
4. Esophageal and Esophagogastric Junction Cancers: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed 7/19/23
5. Gastric Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed 7/19/23
6. Hepatocellular Carcinoma: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed 7/19/23
7. Mesothelioma: Pleural: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/meso_pleural.pdf. Accessed 7/19/23
8. Non-Small Cell Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed 7/19/23
9. Rectal Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed 7/19/23
10. 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
7/19/23	Updated Hepatocellular Indication Specific Criteria (from Hepatobiliary). Added Approval Criteria. Added Mesothelioma: Pleural NCCN Guidelines to References.
11/7/22	Policy approved by P&T
12/12/22	Updated formatting and incorporated universal criteria

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