Ramucirumab (Cyramza®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
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Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of Ramucirumab. 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.

Drug Description

Ramucirumab is a VEGFR2 antagonist that specifically binds VEGFR2 and blocks binding of VEGFR ligands, VEGF-A, VEGF-C, and VEGF-D. As a result, ramucirumab inhibits ligand-stimulated activation of VEGFR2, thereby inhibiting ligand-induced proliferation, and migration of human endothelial cells.

Coverage Determinations

Ramucirumab will require prior authorization. This agent is considered medically necessary for the following indications if all criteria below are met:

FDA Indications[1]

Ramucirumab (Cyramza®) is FDA indicated for the following:

- As a single agent or in combination with paclitaxel, for treatment of advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy.
- In combination with erlotinib, for first-line treatment of metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.
- In combination with docetaxel, for treatment of metastatic non-small cell lung cancer 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 ramucirumab.
- In combination with FOLFIRI, for the treatment of metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.
- As a single agent, for the treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein of ≥400 ng/mL and have been treated with sorafenib.

NCCN Compendium Supported Indications[2]

- Gastric Cancer
- Esophageal and Esophagogastric Junction Cancers
- Non-Small Cell Lung Cancer
- Colon Cancer
- Rectal Cancer
- Hepatocellular Carcinoma

Coverage Determinations[1,2]

Ramucirumab will require prior authorization. This agent may be considered medically necessary for the following oncology indications if all criteria below are met:

Gastric cancer

- The member has a diagnosis of unresectable locally advanced, recurrent, or metastatic gastric cancer with an ECOG performance status 0-2 **AND**
- The member has disease progression or intolerance on or after prior therapy with platinum-based or fluoropyrimidine-based chemotherapy **AND**
- Ramucirumab will be used as subsequent therapy **AND**
- Ramucirumab will be used monotherapy or in combination with paclitaxel

Recommended dosage: 8 mg/kg administered intravenously every 2 weeks

Esophageal cancer

- The member has a diagnosis of unresectable locally advanced, recurrent, or metastatic esophageal adenocarcinoma with an ECOG performance status 0-2 **AND**
- The member has disease progression or intolerance on or after prior therapy with platinum-based or fluoropyrimidine-based chemotherapy **AND**
- Ramucirumab will be used as subsequent therapy **AND**
- Ramucirumab will be used monotherapy or in combination with paclitaxel

Recommended dosage: 8 mg/kg administered intravenously every 2 weeks

Non-small cell lung cancer

- The member has a diagnosis of metastatic non-small cell lung cancer **AND**

- The member has disease progression or intolerance on or after prior therapy with platinum-based chemotherapy **AND**
- For members with EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic aberrations, the member has disease progression on FDA-approved therapy for these aberrations **AND**
- Ramucirumab will be used in combination with docetaxel **OR**
- The member has a diagnosis of metastatic non-small cell lung cancer **AND**
- Ramucirumab will be used in combination with erlotinib for EGFR mutation-positive, advanced or metastatic disease as first-line therapy

Recommended dosage: 10 mg/kg administered intravenously on day 1 of a 21-day cycle

Colorectal cancer

- The member has a diagnosis of unresectable or metastatic colorectal cancer **AND**
- Primary treatment in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin calcium, and irinotecan) for unresectable metachronous metastases and previous treatment with FOLFOX (fluorouracil, leucovorin calcium, and oxaliplatin) or CapeOx (capecitabine, oxaliplatin) as adjuvant therapy has been given within the past 12 months **OR**
- The member has disease progression on or after prior therapy with bevacizumab (or bevacizumab biosimilar product), oxaliplatin, and a fluoropyrimidine (e.g., 5-fluorouracil, capecitabine) **AND**
    - Ramucirumab is given in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) or irinotecan as therapy after first progression of disease if irinotecan was not previously given **AND**
    - *Patient has a documented contraindication to the continued use of bevacizumab or a bevacizumab biosimilar product*

Recommended dosage: 8 mg/kg administered intravenously every 2 weeks

Hepatocellular carcinoma

- The member has unresectable disease and are not a transplant candidate **OR**
- The member is considered inoperable by performance status or comorbidity, or has local disease or local disease with minimal extrahepatic disease only **OR**
- The member has a diagnosis of metastatic hepatocellular carcinoma **AND**
- The member has received prior first-line treatment and experienced progression of disease **AND**
- The member has alpha fetoprotein greater than or equal to 400 ng/mL **AND**
- The member has a Child-Pugh Class A score **AND**
- Ramucirumab will be given as a single agent as subsequent therapy

Recommended dosage: 8 mg/kg administered intravenously every 2 weeks

All indications:

- Ramucirumab will be approved for up to a 12-month duration, or as determined through clinical review.

Coverage Limitations

Treatment with ramucirumab is not considered medically necessary for members with the following concomitant conditions:

- Members that have experienced disease progression while on ramucirumab
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- Warnings/precautions:
    - Hemorrhage
    - Gastrointestinal perforations
    - Impaired wound healing
    - Arterial thromboembolic events
    - Hypertension
    - Infusion-related reactions
    - Worsening of pre-existing hepatic impairment
    - Posterior reversible encephalopathy syndrome
    - Proteinuria including nephrotic syndrome
    - Thyroid dysfunction
    - Embryo-fetal risk

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: injection, ramucirumab, 5 mg
    - J9308

Disclaimer

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

References

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