Ramucirumab (CYRAMZA)
Criteria for Use
December 2022

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ramucirumab.

- ☐ Non-healing wound or fracture
- ☐ Major surgery within prior 28 days
- ☐ Chronic anti-platelet therapy, NSAIDs (including aspirin > 325mg/day)
- ☐ Therapeutic anticoagulation, unless on stabilized outpatient doses
- ☐ Uncontrolled CNS metastases
- ☐ Pre-existing bleeding diathesis or coagulopathy
- ☐ History of GI perforation and/or fistulae within prior 6 months
- ☐ History of gross hemoptysis (defined as bright red blood or ≥ 1/2 teaspoon) within 2 months of therapy initiation
- ☐ Patients with tumor involving major blood vessels or intratumor cavitation
- ☐ Uncontrolled hypertension
- ☐ Severe renal impairment defined as CrCl < 15 ml/min
- ☐ Pre-existing proteinuria (> 2 g urine protein/24 hrs)
- ☐ Severe hepatic impairment defined as bilirubin > 3x Upper Limit of Normal
- ☐ Pregnancy
- ☐ Breastfeeding

Inclusion Criteria

One of the following criteria must be met.

- ☐ Diagnosis of advanced or metastatic gastric or gastro-esophageal Junction (GEJ) adenocarcinoma WITH disease progression on prior fluoropyrimidine- or platinum-containing chemotherapy
- ☐ Diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC) in combination with docetaxel in patients WITH disease progression on prior platinum-based chemotherapy; Patients with EGFR+ or ALK+ disease should have progressed on FDA-approved therapies for those aberrations
- ☐ Diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC) in combination with erlotinib for first-line treatment in patients whose tumors have an EGFR exon 19 deletion or exon 21 (L858R) substitution mutation
- ☐ Diagnosis of metastatic colorectal cancer in combination with FOLFIRI (fluorouracil, leucovorin, irinotecan) WITH disease progression on prior first-line therapy with bevacizumab, oxaliplatin and a fluoropyrimidine
- ☐ Diagnosis of hepatocellular carcinoma Barcelona Clinic Liver Cancer (BCLC) Stage C or B disease refractory or not amendable to locoregional therapy, Child-Pugh Class A and an alpha fetoprotein (AFP) ≥ 400 ng/mL who have been previously treated with sorafenib

Additional Inclusion Criteria *The answers to the following must be fulfilled*

- ☐ Care for the condition provided by VA or VA Community Care oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented.
- ☐ Eastern Cooperative Oncology Group Performance Status 0 – 1

Additional Inclusion Criteria *Select if applicable.*

- ☐ For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 3 months after last dose.

Other Justification

- ☐ _____

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