

# Margetuximab-cmkb (Margenza)

## Criteria for Use

December 2023

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 margetuximab.

- Tumor tissue does not overexpress HER2 protein (Defined as IHC 3+ or FISH amplification ratio greater than or equal to 2.0)
- Known hypersensitivity to margetuximab or any of its excipients (e.g., polysorbate 80, sucrose)
- Untreated and/or unstable brain metastases
- Myocardial infarction, unstable angina, stroke, or transient ischemic attack within 6 months of start
- Clinically significant cardiac arrhythmia requiring treatment
- Uncontrolled hypertension (>180/100 mmHg)
- History of congestive heart failure (New York Heart Association Class 2- 4)
- Baseline left ventricular ejection fraction <50%
- Pericarditis, myocarditis or significant pericardial effusion
- Severe renal impairment (defined as CrCl less than 29 ml/min)
- Moderate or severe hepatic impairment (defined as total bilirubin > 1.5 times the upper limit of normal and any AST)
- Pregnancy
- Lactating

### Inclusion Criteria

All of the following criteria must be met.

- Diagnosis of metastatic breast cancer
- Received 2 or more prior anti-HER2 regimens, with at least one provided in the metastatic setting

### Additional Inclusion Criteria

All of the following criteria must be met:

- Care for the oncologic 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 (ECOG) Performance Status 0 to 1

### Additional Inclusion Criteria (if applicable)

- For patients who may become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 7 months after the last dose of margetuximab