

margetuximab-cmkb (Margenza™)

Place of Service

Office Administration

Infusion Center Administration

Home Infusion Administration

Outpatient Facility Infusion Administration

HCPCS: J9353 per 5 mg

Condition listed in policy (see criteria for details)

- [Breast cancer \(HER2-positive\)](#)

AHFS therapeutic class: Antineoplastic Agents

Mechanism of action: HER2/neu receptor antagonist monoclonal antibody

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for margetuximab-cmkb (Margenza®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer (HER2-positive)

1. Patient has recurrent unresectable or metastatic disease, **AND**
2. Patient is HER2-positive, **AND**
3. Will be used in combination with capecitabine, eribulin, gemcitabine or vinorelbine, **AND**
4. Patient has had at least two prior anti-HER2 regimens

Covered Doses

Up to 15 mg/kg IV every 3 weeks

Coverage Period

Indefinitely

ICD-10:

C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for margetuximab-cmkb (Margenza®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 250 mg/10 mL (25 mg/mL) in a single-dose vial (1 vial)
- 250 mg/10 mL (25 mg/mL) in a single-dose vial (4 vials)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Margenza® (margetuximab-cmkb) [Prescribing information]. Rockville, MD: MacroGenics, Inc.; 5/2023.
- National Comprehensive Cancer Network. Breast Cancer (Version 3.2022). Available at www.nccn.org.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*