

## Medical Policy:

### Margenza® (margetuximab) injection for intravenous use

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.335	March 18, 2025	June 9, 2021

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Margetuximab-cmkb is a human epidermal growth factor receptor 2 protein (HER2)/neu receptor antagonist that binds to the extracellular domain of the HER2 receptor. Upon binding to HER2-expressing tumor cells, margetuximab-cmkb inhibits tumor cell proliferation, reduces shedding of the HER2 extracellular domain, and mediates antibody-dependent cellular cytotoxicity (ADCC).

## Length of Authorization

Coverage is provided for 1 year and may be renewed.

## Dosing Limits [Medical Benefit]

The recommend dosage is 15 mg/kg once every 3 weeks (350 billable units (1,750 mg) every 21 days)

## Guideline

### I. INITIAL APPROVAL CRITERIA

#### 1. Metastatic breast cancer

Coverage is provided if the patient meets the following criteria (A, B, C, D, E, and F)

- A. Patient is  $\geq$  18 years of age; **AND**
- B. Patient has diagnosis of recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer; **AND**
- C. The medication will be used in combination with systemic chemotherapy; **AND**  
*Note: Examples of chemotherapy are capecitabine, eribulin, gemcitabine, vinorelbine.*
- D. Patient has tried and failed 2 or more prior anti-HER2 regimens, at least one of which was for metastatic disease; **AND**  
*Note: Some examples of anti-HER2 regimens are Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Kadcyla (ado-trastuzumab emtansine intravenous infusion), Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion), Tukysa (tucatinib tablets) + trastuzumab + capecitabine, trastuzumab + lapatinib, trastuzumab + docetaxel, trastuzumab + vinorelbine, Nerlynx (neratinib tablets) + capecitabine.*
- E. Prescribed by or in consultation with an oncologist or hematologist; **AND**
- F. The requested use is supported by FDA-approved prescribing information OR the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines<sup>®</sup>) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium<sup>®</sup>) with a recommendation of category level 1 or 2A.

## II. Renewal Criteria

Coverage can be renewed for 1 year based on the following criteria:

1. Member is responding positively to therapy as demonstrated by tumor response or lack of disease progression; **AND**
2. There is absence of unacceptable toxicity from the drug.  
*Examples of unacceptable toxicity include: left ventricular dysfunction, infusion related reactions, etc*

## Applicable Procedure Codes

Code	Description
J9353	Injection, margetuximab-cmkb, 5 mg

## Applicable NDCs

Code	Description
74527-0022-XX	Single-dose vial: 250 mg/10 mL, IV Solution

## ICD-10 Diagnoses

Code	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast

C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/18/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	2/2/2024	Annual Review: Added recurrent disease as an option, added examples of HER2 Regimens, Chemotherapy and toxicity.
EmblemHealth & ConnectiCare	6/5/2023	Annual Review: No criteria changes Removed code Z85.3
EmblemHealth & ConnectiCare	09/07/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	06/09/2021	New Policy

## References

1. Margenza™(margetuximab-cmkb) Injection [package insert]. Rockville, MD. MacroGenics, Inc. Updated January 21, 2021. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e97a5872-eabf-463b-8f4c-5b5aed9c7bf0>. Accessed March 31, 2021.
2. Margenza™(margetuximab-cmkb) Injection. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated January 4, 2021. Accessed March 31, 2021.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology. Breast cancer (version 1.2021 – January 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 31, 2021.
4. National Cancer Institute Surveillance, Epidemiology, and End Results Program (SEER). Cancer Stat Facts: Female Breast Cancer. Available at: <https://seer.cancer.gov/statfacts/html/breast.html>. Accessed on March 8, 2021.
5. Waks AG, Winer EP. Breast cancer treatment. A review. *JAMA*. 2019;321:288-300.