Medical Policy:

Margenza® (margetuximab) injection for intravenous use

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

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. <u>Metastatic breast cancer</u>

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

A. Patient is ≥ 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®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) 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.