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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/12/2026

Margenza™ (margetuximab-cmkb)

HPCPS: J9353

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by or in consultation with an oncologist
 - d. HER2 positive is defined as follows
 - i. Immunohistochemistry (IHC) is 3+
OR
 - ii. In situ hybridization (ISH) positive by any of the following
 - 1. Single probe average HER2 copy number greater than or equal to 6.0 signals/cell
OR
 - 2. Dual probe HER2/CEP17 ratio greater than or equal to 2.0
OR
 - 3. Dual probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell
 - e. Must have had disease progression or toxicity while on two or more prior anti-HER2-based regimens, one of which is for metastatic disease
 - f. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Continuation of therapy until unacceptable toxicity or disease progression

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Margetenza is a HER-2 receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.
- Per the 2022 National Comprehensive Cancer Network breast cancer treatment guidelines, patients are eligible for adjuvant HER2-directed treatment if they have HER2-positive breast cancer defined as:
 - Single probe average HER2 copy number greater than or equal to 6.0 signals/cell
OR
 - Dual probe HER2/CEP17 ratio greater than or equal to 2.0
OR
 - Dual probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell

References:

1. Margetenza [prescribing information]. Rockville, MD: MacroGenics, Inc.; February 2025.
2. National Comprehensive Cancer Network. Breast cancer (Version 5.2025). 2025 Oct 16. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed on December 12, 2025.
3. Clinicaltrials.gov. A phase 3, randomized study of margetuximab plus chemotherapy vs trastuzumab plus chemotherapy in the treatment of patients with HER2+ metastatic breast cancer who have received prior anti-HER2 therapies and require systemic treatment (NCT02492711). Available at: <https://clinicaltrials.gov/ct2/show/NCT02492711>. Accessed on December 21, 2020.

Policy History												
#	Date	Change Description										
1.6	Effective Date: 02/12/2026	Annual review of criteria was performed, no changes were made										
1.5	Effective Date: 02/13/2025	Annual review of criteria was performed, no changes were made										
1.4	Effective Date: 02/08/2024	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 02/02/2023	Updated approval length to allow for FDA recommended dosing for at least 60 days and up to 6 months at a time										
1.2	Effective Date: 02/10/2022	Annual review of criteria was performed, no changes were made										
1.1	Effective Date: 04/22/2021	UM medical management system update for BCBS, BCN, MAPPO, and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
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MAPPO	Yes											
BCNA	Yes											
1.0	Effective Date: 02/04/2021	New policy <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.