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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: 04/16/2026

Kadcyla[®] (ado-trastuzumab emtansine)

HCPCS: J9354

Policy:

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

A. Criteria

- a. FDA approved indication
- b. FDA approved age
- c. 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
- d. Previously received trastuzumab and a taxane, separately or in combination
OR
- e. Developed disease recurrence during or within six months of completing adjuvant therapy for metastatic breast cancer or have residual invasive disease after completion of neoadjuvant therapy
- f. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list

B. Quantity Limitations, Authorization Period, and Renewal Criteria

- a. Quantity Limits: Align with FDA approved dosing
- b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 months and up to 6 months at a time
- c. Renewal Criteria:
 - i. Metastatic breast cancer: No evidence of disease progression
 - ii. Early breast cancer with residual disease: Not eligible for renewal after 14 cycles of therapy

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:

- Kadcylla is a HER2-targeted antibody and microtubule inhibitor conjugate indicated
 - As a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination in patients who have either:
 - Received prior therapy for metastatic disease, or
 - Developed disease recurrence during or within six months of completing adjuvant therapy
 - The adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment
- Per the NCCN guidelines for breast cancer, 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. Kadcylla [package insert]. San Francisco, CA: Genentech Inc; May 2025.
2. Burstein & Harold MD. Adjuvant medical therapy for HER2 positive breast cancer. Uptodate.com. March 2013.
3. Hogan K. Preliminary medication review antineoplastics: ado-trastuzumab emtansine (Kadcyla) [Genentech]. RegenceRx; 2013.
4. TEC Specialty Pharmacy Report. Ado-trastuzumab emtansine (Kadcyla) 03-2013.
5. National Comprehensive Cancer Network. Breast cancer (Version 1.2026). 2026 Jan 16. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed on February 18, 2026.

Policy History												
#	Date	Change Description										
2.5	Effective Date: 04/16/2026	Updated to include the trial and failure of preferred products statement										
2.4	Effective Date: 04/10/2025	Annual review of criteria was performed, no changes were made										
2.3	Effective Date: 04/11/2024	Annual review of criteria was performed, no changes were made										
2.2	Effective Date: 04/06/2023	Updated approval length to allow for no less than a 60 day approval duration										
2.1	Effective Date: 06/09/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time										
2.0	Effective Date: 06/10/2021	Annual review of criteria was performed, no changes were made										
1.9	Effective Date: 12/01/2020	UM medical management system update for BCBS <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											
BCN	Yes											
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BCNA	Yes											
1.8	Effective Date: 06/11/2020	Annual review of criteria was performed, no changes were made										
1.7	Effective Date: 01/01/2020	UM medical management system update for 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>No</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	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	No											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.6	Effective Date: 06/06/2019	Updated with new indication										
1.5	Effective Date: 11/01/2018	Updated criteria per oncology vendor										
1.4	Effective Date: 08/09/2018	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 08/10/2017	Annual review of criteria was performed, no changes were made										
1.2	Effective Date: 08/11/2016	Annual review of criteria was performed, no changes were made										

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1.1	Effective Date: 07/01/2015	UM medical management system update for BCN										
		<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>Yes</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	Yes	MAPPO	No	BCNA	No
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BCBS	No											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.0	Effective Date: 08/08/2013	Initial Criteria Write-Up										

** 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>.*