

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Kadcyla (ado-trastuzumab emtansine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Kadcyla (ado-trastuzumab emtansine)

APPROVAL CRITERIA

Requests for Kadcyla (ado-trastuzumab emtansine) may be approved if the following criteria are met:

- I. Individual has a diagnosis of HER2-positive (HER2+) breast cancer (NCCN 1) confirmed by one of the following:
 - A. Immunohistochemistry (IHC) is 3+; **OR**
 - B. In situ hybridization (ISH) positive;

AND

- II. Individual is using as monotherapy;

AND

- III. Individual is using as adjuvant treatment of early non-metastatic breast cancer for residual invasive disease in the breast or axilla after surgery after receiving at least 6 cycles (16 weeks) of neoadjuvant therapy containing a taxane (with or without anthracycline) and trastuzumab (or trastuzumab biosimilars);

OR

- IV. Individual has metastatic breast cancer disease; **AND**
- V. Individual has previously received trastuzumab (or trastuzumab biosimilars) and a taxane, separately or in combination; **AND**
- VI. Individual has either received prior therapy for metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy.

Requests for Kadcyla (ado-trastuzumab) may not be approved for the following:

- I. When the above criteria are not met and for all other indications; **OR**
- II. When Kadcyla (ado-trastuzumab emtansine) is used in combination with other targeted biologic agents or chemotherapy agents.

Key References:

CRX-ALL-0548-20

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	X	X	X	X	X

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 28, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. Li BT, Shen R, Buonocore D, et al. Ado-trastuzumab emtansine in patients with HER2 mutant lung cancers. Results from a phase II basket trial. J.Clin Oncol 2018;36:2532-2537.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 28, 2020.
 - a. Breast Cancer. V1.2020. Revised January 15, 2020.
 - b. Non-Small Cell Lung Cancer. V2.2020. Revised December 23, 2019.

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