

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

- IV. Individual has metastatic breast cancer disease; **AND**
- V. Individual has previously received trastuzumab 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.

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

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: April 9, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 9, 2019.
 - a. Breast Cancer. V1.2019. Revised March 14, 2019.
 - b. Gastric Cancer. V1.2019. Revised March 14, 2019.
 - c. Non-Small Cell Lung Cancer. V3.2019. Revised January 18, 2019.

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.