

## Kadcyla (ado-trastuzumab emtansine)

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**Line(s) of Business:**

HMO; PPO; QUEST Integration  
Medicare Advantage

**Original Effective Date:**

10/01/2015

**Current Effective Date:**

03/01/2018

### POLICY

#### A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

- Metastatic breast cancer
  - Kadcyla, as a single agent, is indicated for the treatment of patients with *HER2*-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy.

##### Compendial Use

- Single-agent therapy for recurrent or metastatic *HER2*-positive disease:
  - With symptomatic visceral disease or visceral crisis
  - That is hormone-receptor negative or hormone-receptor positive and endocrine therapy refractory

#### B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- For initial therapy
  - Current oncology notes, clinical notes (including previous treatment history), and any pertinent pathology reports and/or imaging studies
  - Human epidermal growth factor receptor 2 (HER2) test result
  - Hormone receptor test result (if applicable)
- For continuation therapy
  - Documentation demonstrating lack of disease progression on therapy

#### C. PRESCRIBER RESTRICTION

- Kadcyla must be prescribed by an oncologist.

**D. CRITERIA FOR APPROVAL****Breast Cancer**

Authorization of 3 months may be granted for members who are prescribed Kadcyla as a single agent for HER2-positive recurrent or metastatic breast cancer when one of the following criteria is met:

- a. Member has symptomatic visceral disease or visceral crisis
- b. Tumor is either hormone-receptor negative or hormone-receptor positive and endocrine therapy refractory

**E. CONTINUATION OF THERAPY**

1. No previous authorization/precertification:

All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.

2. Reauthorization:

Members who were previously approved for Kadcyla by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 3 months may be granted if the following information is supplied:

- A current oncology note documenting the patient's response to treatment showing no progression of disease
- Current imaging studies and other objective measures showing no progression of disease when compared with previous results

**F. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**G. ADMINISTRATIVE GUIDELINES**

Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

**H. IMPORTANT REMINDER**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

**I. REFERENCES**

1. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; July 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 21, 2017.

**Document History**

10/01/2015	Original effective date
05/2016	Annual review
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07/2017	Annual review
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