Kadcyla (ado-trastuzumab emtansine)

**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.1

**Compendial Use**

- Single-agent therapy for recurrent or metastatic HER2-positive disease2:
  - 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

Authorization of 3 months may be granted to members requesting authorization for continuation of therapy when ALL of the following criteria are met:

a. Member has not had disease progression.
b. Previous Kadcyla therapy was authorized by HMSA or member meets all initial criteria.

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


Revised: May 2016.