**Draft Revised Policy: Do Not Implement**

# Ado-Trastuzumab Emtansine (Kadcyla®)

## IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:**

## POLICY

### 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 Indications

Metastatic Breast Cancer (MBC)
Kadcyla, as a single agent, is indicated for the treatment of patients with human epidermal growth factor receptor 2 (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.

Early Breast Cancer (EBC)
Kadcyla, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.

Compendial Uses

- Single-agent therapy for recurrent or stage IV (M1) HER2-positive breast cancer
- Non-small cell lung cancer with HER2 mutations
- HER2-positive recurrent, unresectable or metastatic salivary gland tumors

All other indications are considered experimental/investigational and not medically necessary.

### DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

### COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

**Breast Cancer**

- Authorization of 12 months may be granted for subsequent treatment of HER2-positive metastatic or recurrent breast cancer or for HER2-positive breast cancer with no response to preoperative systemic therapy when used as a single agent.

- Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive early breast cancer when used as a single agent.
- Authorization of 12 months may be granted for initial treatment of small asymptomatic brain metastases in HER2-positive breast cancer when used as a single agent.

**Non-Small Cell Lung Cancer**

Authorization of 12 months may be granted for subsequent treatment of non-small cell lung cancer with HER2 (ERBB2) mutations when all ~~both~~ of the following criteria are met:

- The disease is recurrent, advanced or metastatic
- The requested medication will be used as a single agent
- The member has not experienced disease progression on a HER2 targeted drug (e.g., Enhertu, Kadcyla)

**Salivary Gland Tumor**

Authorization of 12 months may be granted for treatment of recurrent, unresectable or metastatic HER2-positive salivary gland tumors as a single agent.

**CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section ~~III~~ when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

**MEDICATION QUANTITY LIMITS**

| Drug Name | Diagnosis | Maximum Dosing Regimen |
|---|---|---|
| Kadcyla (Ado-trastuzumab emtansine) | Breast Cancer, metastatic or early, Non-Small Cell Lung Cancer, Salivary Gland Tumor | Route of Administration: Intravenous<br>3.6mg/kg every 3 weeks |

**APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS**

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

**ADDITIONAL INFORMATION**

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

**REFERENCES**

1. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed September 3, 2024.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 4.2024. Accessed September 3, 2024. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf

**EFFECTIVE DATE**

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