Reference number(s)
2471-A

STANDARD MEDICARE PART B MANAGEMENT

KADCYLA (ado-trastuzumab emtansine)

POLICY

I. 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.

A. FDA-Approved Indications

1. 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.

2. 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.

B. Compendial Uses

1. Single-agent therapy for recurrent or stage IV (M1) HER2-positive breast cancer
2. Non-small cell lung cancer with HER2 mutations
3. HER2-positive recurrent salivary gland tumors

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: human epidermal growth factor receptor 2 (HER2) status.

III. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer

1. 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.
2. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive early breast cancer when used as a single agent.

B. **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 both of the following criteria are met:
1. The disease is recurrent, advanced or metastatic
2. The requested medication will be used as a single agent

C. **Salivary gland tumor**
Authorization of 12 months may be granted for treatment of recurrent HER2-positive salivary gland tumors as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are continuing with the requested medication when all of the following criteria are met. Adjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

A. The member is currently receiving treatment with the requested medication.
B. The requested medication is being used to treat a diagnosis or condition enumerated in Section III.
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen AND
   2. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Kadcyla.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: Non-small cell lung cancer
4. NCCN Guideline: Breast cancer
5. NCCN Guideline: Central nervous system cancers
6. NCCN Guideline: Head and neck cancers

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Kadcyla are covered in addition to the following:

1. Single-agent therapy for recurrent or stage IV (M1) HER2-positive breast cancer
2. Non-small cell lung cancer with HER2 mutations
3. HER2-positive recurrent salivary gland tumors

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VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for single-agent therapy for recurrent or stage IV (M1) HER2-positive breast cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for non-small cell lung cancer with HER2 mutations can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for HER2-positive recurrent salivary gland tumors can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VII. REFERENCES

1. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 6, 2022.