

Specialty Guideline Management

Kadcyla

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kadcyla	ado-trastuzumab emtansine

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 Indications¹

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.

Reference number(s)
1906-A

Compendial Uses²⁻⁴

- 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

Breast Cancer^{1,2,4}

- 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 12 months may be granted for first-line therapy of HER2-positive metastatic or recurrent breast cancer as a single agent or in combination with pertuzumab if taxane-based therapy is unsuitable.
- Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer when used as a single agent.
- Authorization of 12 months may be granted for treatment of brain metastases in HER2-positive breast cancer when used as a single agent or in combination with neratinib.

Non-Small Cell Lung Cancer²

Authorization of 12 months may be granted for subsequent treatment of non-small cell lung cancer with HER2 (ERBB2) mutations when all 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)

Salivary Gland Tumor^{2,3}

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

Reference number(s)
1906-A

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 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.

References

1. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; May 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed September 9, 2025.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 5.2025. Accessed September 9, 2025. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.
4. Micromedex [electronic version]. Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com>. Accessed September 22, 2025.