PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Kadcyla Prior Authorization Policy
- Kadcyla® (ado-trastuzumab emtansine intravenous infusion – Genentech)

REVIEW DATE: 08/28/2024

OVERVIEW

Kadcyla, a human epidermal growth factor receptor 2 (HER2)-targeted antibody and microtubule inhibitor conjugate, is indicated for the treatment of patients with HER2-positive breast cancer as a single agent for the following uses:[1]

- **Early breast cancer**, for the adjuvant treatment in patients who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.
- **Metastatic breast cancer**, in patients 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 6 months of completing adjuvant therapy.

Guidelines

Kadcyla is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Breast Cancer:** NCCN guidelines (version 4.2024 – July 3, 2024) recommend Kadcyla as a "Preferred" adjuvant therapy in patients who have residual disease after receiving neoadjuvant (preoperative) therapy (category 1).[2-3] Kadcyla is also recommended for the treatment of HER2-positive recurrent unresectable (local or regional) or Stage IV metastatic disease as a preferred second line regimen (category 2A).
- **Head and Neck Cancers:** NCCN guidelines (version 4.2024 – May 1, 2024) recommend Kadcyla as a systemic therapy option for recurrent, unresectable, or metastatic salivary gland tumors (under "Useful in Certain Circumstances") for HER2 positive tumors (category 2A).[3,4]
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 7.2024 – June 26, 2024) recommend Kadcyla for erb-b2 receptor tyrosine kinase 2 (ERBB2) or HER2 mutations (category 2A).[3,5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Kadcyla. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Kadcyla, as well as the monitoring required for adverse events and long-term efficacy, approval requires Kadcyla to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kadcyla is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Breast Cancer.** Approve if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   C) Patient meets ONE of the following (i or ii):
      i. Approve for 1 year if Kadcyla is used for recurrent or metastatic breast cancer; OR
      ii. Approve for 1 year (total) if Kadcyla will be used as adjuvant therapy; AND
   D) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

2. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has metastatic disease; AND
   C) The disease has activating human epidermal growth factor receptor 2 (HER2)-mutations; AND
   D) The medication is prescribed by or in consultation with an oncologist.

3. **Salivary Gland Tumor**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has recurrent, unresectable, or metastatic disease; AND
   C) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   D) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kadcyla is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kadcyla® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; February 2022.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – July 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 23, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 23, 2024. Search term: ado-trastuzumab emtansine.
4. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 4.2024– May 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 23, 2024.
5. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – June 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 23, 2024.