

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Kadcyła Prior Authorization Policy

- Kadcyła® (ado-trastuzumab emtansine intravenous infusion – Genentech)

REVIEW DATE: 08/17/2022

OVERVIEW

Kadcyła, 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

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

- **Breast Cancer:** NCCN guidelines (version 4.2022 – June 21, 2022) recommend Kadcyła as a preferred adjuvant therapy in patients who have residual disease after receiving neoadjuvant (preoperative) therapy (category 1).²⁻³ Kadcyła 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).²⁻³
- **Head and Neck Cancers:** NCCN guidelines (version 2.2022 – April 26, 2022) recommend Kadcyła as a systemic therapy option for recurrent, unresectable, or metastatic salivary gland tumors (useful in certain circumstances) for HER2 positive tumors (category 2A).^{3,4}
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 3.2022 – March 16, 2022) recommend Kadcyła for erb-b2 receptor tyrosine kinase 2 (ERBB2) or HER2 mutations NSCLC (category 2A).^{3,5}

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. Breast Cancer. Approve if the patient meets the following criteria (A, B, C, and D):

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- 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 criteria (i or ii):
 - i. Approve for 1 year if Kadcyła is used for recurrent or metastatic breast cancer; OR
 - ii. Approve for 1 year (total) if Kadcyła 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 the following criteria (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 the following criteria (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 Kadcyła 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. Kadcyła® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; February 2022.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – June 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 11, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 11, 2022. Search term: ado-trastuzumab emtansine.
4. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 2.2022– April 26, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 11, 2022.
5. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – March 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 11, 2022.