Utilization Review Policy 167

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

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 08/30/2023

COVERAGE CRITERIA FOR: All UCare Plans

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 in the following settings:[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.

Dosing

Kadcyla doses of up to 3.6 mg per kg administered by intravenous infusion once every 3 weeks are recommended in the product labeling for approved uses.[1] Patients with early breast cancer should receive treatment for a total of 14 cycles unless there is disease recurrence or unmanageable toxicity. Kadcyla doses of up to 3.6 mg per kg administered by intravenous infusion once every 3 weeks was used in a clinical study for non-small cell lung cancer and salivary gland tumors.[2,3]

Kadcyla should not be administered at doses greater than 3.6 mg per kg.[1] The dose of Kadcyla should not be re-escalated after a dose reduction is made. The administration schedule should be adjusted to maintain a 3-week interval between doses.

Guidelines

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

- **Breast Cancer:** NCCN guidelines (version 4.2023 – March 23, 2023) recommend Kadcyla as a preferred adjuvant therapy in patients who have residual disease after receiving neoadjuvant (preoperative) therapy (category 1).[4,5] 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).[4,5]
- **Head and Neck Cancers:** NCCN guidelines (version 2.2023 – May 15, 2023) recommend Kadcyla as a systemic therapy option for recurrent, unresectable, or metastatic salivary gland tumors (useful; in certain circumstances) for HER2 positive tumors (category 2A).[5,6]
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 3.2023 – April 13, 2023) recommend Kadcyla for erb-b2 receptor tyrosine kinase 2 (ERBB2) or HER2 mutations (category 2A).[5,7]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Kadcyla. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing

documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 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.

   Dosing. Approve up to a maximum dose of 3.6 mg/kg administered by intravenous infusion not more frequently than once every 3 weeks.

Other Uses with Supportive Evidence

2. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets 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.

   Dosing. Approve up to a maximum dose of 3.6 mg/kg administered by intravenous infusion not more frequently than once every 3 weeks.

3. **Salivary Gland Tumor**. Approve for 1 year if the patient meets 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.

   Dosing. Approve up to a maximum dose of 3.6 mg/kg administered by intravenous infusion not more frequently than once every 3 weeks.

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. Li BT, Shen R, Buonocore D, et al. Ado-trastuzumab emtansine for patients with HER2-mutant lung cancers: Results from a Phase II basket trial. *J Clin Oncol.* 2018;36:2532-2537.
3. Jhaveri KL, Wang XV, Makker V. Ado-trastuzumab emtansine (T-DM1) in patients with HER2-amplified tumors excluding breast and gastric/gastroesophageal junction (GEJ) adenocarcinomas: results from the NCI-MATCH trial (EAY131) subprotocol Q. *Ann Oncol*. 2019;30(11):1821-1830.
4. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – March 23, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 22, 2023.
5. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 22, 2023. Search term: ado-trastuzumab emtansine
6. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 2.2023 – May 15, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 22, 2023.
7. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 22, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Non-Small Cell Lung Cancer:** The requirement that the patient has metastatic disease was added. The criterion, "Patient has human epidermal growth factor receptor 2 (HER2)-positive disease" was reworded to, "The disease has activating human epidermal growth factor receptor 2 (HER2)-mutations."	08/17/2022
Annual Revision	No criteria changes	08/30/2023