VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 08/18/2021

OVERVIEW

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

- **Early breast cancer**, as a single agent, for the adjuvant treatment in patients who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.
- **Metastatic breast cancer**, as a single agent, 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. 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.[2]

Kadcyla should not be administered at doses greater than 3.6 mg per kg. 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 5.2021 – June 28, 2021) recommend Kadcyla as a preferred adjuvant therapy in patients who have residual disease after receiving neoadjuvant (preoperative) therapy (category 1).[3-4] 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).[3-4]
- **Head and Neck Cancers:** NCCN guidelines (version 3.2021 – April 27, 2021) 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).[4,5]
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 6.2020 – June 15, 2020) recommend Kadcyla for HER2 mutation-positive NSCLC (category 2A).[4,6]

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 Indications

1. **Breast Cancer.** Approve if the patient meets the following criteria (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 criteria (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
   - **C)** Kadcyla is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to a maximum dose of 3.6 mg per 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 criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has human epidermal growth factor receptor 2 (HER2)-positive non-small cell lung cancer; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to a maximum dose of 3.6 mg per 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 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.

   Dosing. Approve up to a maximum dose of 3.6 mg per 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; September 2020.
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. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 5.2021 – June 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 29, 2021.
4. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 29, 2021. Search term: ado-trastuzumab emtansine
5. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 3.2021– April 27, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 28, 2021.
6. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2021– June 15, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 28, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	08/12/2020
Annual Revision	**Breast Cancer:** A requirement was added that the patient is ≥ 18 years of age. **Non-Small Cell Lung Cancer (NSCLC):** A requirement was added that the patient is ≥ 18 years of age. **Salivary Gland Tumor:** Indication and criteria were added to other uses with supportive evidence based on NCCN guideline recommendations.	08/18/2021