PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Kadcyla® (ado-trastuzumab emtansine for intravenous [IV] injection – Genentech, Inc.)

APPROVAL DATE: 07/24/2019

OVERVIEW

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 Herceptin® (trastuzumab for intravenous [IV] infusion) and a taxane, separately or in combination.[1] Patients should have either received prior therapy for metastatic disease, or developed disease recurrence during or within 6 months of completing adjuvant therapy. Kadcyla, as a single agent, is also 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.

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 2.2019 – July 2, 2019) 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 or Stage IV metastatic disease (category 2A).

The NCCN non-small cell lung cancer (NSCLC) guidelines (version 5.2019 – June 7, 2019) and Compendium recommend Kadcyla for HER2 mutation-positive NSCLC (category 2A).[3,4]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Kadcyla. All approvals are provided for the duration noted below. Because of the 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, initial 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 the following criteria:

FDA-Approved Indications

1. **Breast Cancer.** Approve if the patient meets the following criteria (A, B, and C):
   - **A)** Kadcyla is prescribed by or in consultation with an oncologist; AND
   - **B)** The patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **C)** The 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.

Other Uses with Supportive Evidence

2. Non-Small Cell Lung Cancer (NSCLC). Approve for 1 year if the patient meets the following criteria (A and B):

A) The medication is prescribed by or in consultation with an oncologist; AND

B) The patient has human epidermal growth factor receptor 2 (HER2) mutation-positive NSCLC.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Kadcyla has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (

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® for intravenous injection [prescribing information]. South San Francisco, CA: Genentech, Inc.; July 2016.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 2.2019 – July 2, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 16, 2019.
3. The NCCN Drugs & Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 16, 2019. Search term: ado-trastuzumab emtansine.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 5.2019 – June 7, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 16, 2019.