Clinical Policy: Ado-Trastuzumab (Kadcyla)

Reference Number: PA.CP.PHAR.229
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

Description
Ado-trastuzumab emtansine (Kadcyla®) is a human epidermal growth factor receptor 2 protein (HER2)-targeted antibody and microtubule inhibitor conjugate.

FDA Approved Indication(s)
Kadcyla is indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer 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 six months of completing adjuvant therapy.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Kadcyla is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis recurrent or metastatic HER2-positive breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 3.6 mg/kg every 21 days;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Non-Small Cell Lung Cancer (off-label) (must meet all):

1. Diagnosis of HER2-positive non-small cell lung cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 3.6 mg/kg every 21 days;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 3.6 mg/kg every 21 days;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

   Approval Duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2 protein

Appendix B: Therapeutic Alternatives
Not applicable.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	3.6 mg/kg IV Q3WK (21-day cycle) until disease progression or unacceptable toxicity.	3.6 mg/kg

V. Product Availability

Single-use vial: 100 mg, 160 mg

VI. References

1. Kadcyla Prescribing Information. South San Francisco, CA: Genentech, Inc.; December 2018. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed January 31, 2019.
2. Ado-trastuzumab emtansine. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 31, 2019.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9354	Injection, ado-trastuzumab emtansine, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review;; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; off-label NSCLC added; references reviewed and updated.	02.13.18	
2Q 2019 annual review: references reviewed and updated.	04/19	