Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2022**
Policy Number: PA.CP.PHAR.229	**Effective Date: 01/2018** **Revision Date: 04/2022**
Policy Name: Ado-Trastuzumab (Kadcyla)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2022 annual review: added criterion for single-agent therapy for off-label indications of NSCLC and salivary gland tumor per NCCN; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Ado-Trastuzumab (Kadcyla)

Reference Number: PA.CP.PHAR.229
Effective Date: 01/18
Last Review Date: 04/2022 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:

- Adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.
- 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 PA Health & Wellness® that Kadcyla is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all):
1. Diagnosis of HER2-positive breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single-agent;
5. Documentation of prior use of trastuzumab-based therapy and a taxane;
6. Request meets one of the following (a, b, or c):
   a. As adjuvant: Dose does not exceed 3.6 mg/kg every 21 days for a maximum of 14 doses;
   b. For metastatic: Dose does not exceed 3.6 mg/kg every 21 days;
   c. 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. Additional NCCN Recommended Uses (off-label) (must meet all):
1. Diagnosis of one of the following (a, b or c):
   a. HER2-positive non-small cell lung cancer (NSCLC);
   b. Salivary gland tumor and meets both of the following (i and ii):
      i. Disease is HER2-positive;
      ii. Disease is recurrent, unresectable, or metastatic;
   c. Other category 1, 2A, or 2B NCCN-recommended uses not listed;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Prescribed as a single agent for NSCLC or Salivary gland tumor;
5. 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 PA Health & 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. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. As adjuvant therapy for breast cancer: New dose does not exceed 3.6 mg/kg every 21 days for a maximum of 14 doses;
   b. For all other indications: New dose does not exceed 3.6 mg/kg every 21 days;
   c. New 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 PA Health & 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
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives
Not applicable.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): hepatotoxicity, cardiac toxicity, and embryo-fetal toxicity

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	*Adjuvant therapy for early breast cancer with residual disease* 3.6 mg/kg IV Q3WK (21-day cycle) for a total of 14 cycles unless there is disease recurrence or unmanageable toxicity. *Metastatic breast cancer* 3.6 mg/kg IV Q3WK (21-day cycle) until disease progression or unmanageable 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.; February 2022. Available at: https://www.gene.com/download/pdf/kadcyla_prescribing.pdf. Accessed February 15, 2022.
2. Ado-trastuzumab emtansine. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 15, 2022.
3. Minckwitz GV, Huang CS, Mano MS, et al. Trastuzumab emtansine for residual invasive HER2-positive breast cancer. N Engl J Med 2019;380:617-28.

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.	02/2018	
2Q 2019 annual review: references reviewed and updated.	04/2019	
2Q 2020 annual review: added criteria for Breast Cancer to align with FDA labeling language; added dosing information for adjuvant therapy in early breast cancer with residual disease; references reviewed and updated.	04/2020	

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2021 annual review: combined NSCLC and new off-label salivary gland tumor indications supported by NCCN into one off-label section under I.B.; references reviewed and updated.	04/2021	
2Q 2022 annual review: added criterion for single-agent therapy for off-label indications of NSCLC and salivary gland tumor per NCCN; references reviewed and updated.	04/2022	