Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 108.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Kadcyla (ado-trastuzumab emtansine)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Kadcyla (ado-trastuzumab emtansine)

II. Purpose/Objective:
To provide a policy of coverage regarding Kadcyla (ado-trastuzumab emtansine)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Kadcyla (ado-trastuzumab emtansine) is a HER2-antibody drug conjugate which incorporates the HER2 targeted actions of trastuzumab with the microtubule inhibitor DM1 (a maytansine derivative). The conjugate, which is linked via a stable thioether linker, allows for selective delivery into HER2 overexpressing cells, resulting in cell cycle arrest and apoptosis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Kadcyla (ado-trastuzumab emtansine) will be considered medically necessary for all lines of business when all of the following criteria are met:

For Treatment of Early Breast Cancer:
- Prescribed by hematologist/oncologist **AND**
- Physician supplied documentation of HER2-positive early breast cancer **AND**
- Physician supplied documentation of neoadjuvant treatment with trastuzumab and a taxane **AND**
- Physician supplied documentation of residual invasive disease detected in the surgical specimen of the breast or axillary nodes after completion of neoadjuvant therapy.

AUTHORIZATION DURATION: Approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Kadcyla for the treatment of early breast cancer should not exceed the FDA-approved treatment duration of 14 cycles. For requests exceeding the above limit, medical record documentation of the following is required:
- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

For Treatment of Metastatic Breast Cancer:
- Prescribed by a hematologist/oncologist **AND**
- Physician supplied documentation of a diagnosis of HER2-positive, metastatic breast cancer **AND**
- Physician supplied documentation of previous treatment with trastuzumab and a taxane separately or in combination and one of the following:
    - Received prior therapy for metastatic disease OR
    - Developed disease recurrence during or within six months of completing adjuvant therapy.

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Kadcyla [prescribing information]. South San Francisco, CA: Genentech, Inc; April 2022.
2. Minchwitz GV, Huang CS, Mano Ms, et al. Trastuzumab Emtansine for Residual Invasive HER2-Positive Breast Cancer. Massachusetts Medical Society. New England Journal of Medicine (NEJM); 2019 Feb 14; 380:617-628 [cited 2023 Dec 27]. Available from: https://www.nejm.org/doi/full/10.1056/nejmoa1814017

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/21/13

Revised: 08/14 (grammatical corrections) 3/24/15 (formatting, auth duration), 7/16/19 (early breast cancer), 5/11/22 (Medicaid PARP statement), 5/8/23 (LOB carve out, Medicaid business segment), 12/31/23 (references added), 4/22/25 (description, removed brands, LOB table, taglines)

Reviewed: 08/14, 3/16, 3/30/17, 3/29/18, 1/30/19, 7/1/20, 5/27/21, 4/23/24

MA UM Committee approval: 12/31/23, 12/31/24, 6/9/25

DHS PARP approval: 5/16/25