

Clinical Policy: Ado-Trastuzumab Emtansine (Kadcyla)

Reference Number: CP.PHAR.229

Effective Date: 06.01.16

Last Review Date: 08.19

Line of Business: Commercial, Medicaid, HIM-Medical Benefit

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] 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 \geq 18 years;
4. Prescribed as a single-agent therapy;
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:

Medicaid/HIM-Medical Benefit – 6 months

Commercial – 6 months or to the member's renewal date, whichever is longer

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

1. Diagnosis of HER2-positive non-small cell lung cancer (NSCLC);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 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:

Medicaid/HIM-Medical Benefit – 6 months

Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Kadcyla for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
 - a. As adjuvant for breast cancer: New dose does not exceed 3.6 mg/kg every 21 days for a maximum of 14 doses;
 - b. For metastatic breast cancer or NSCLC: 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:

Medicaid/HIM-Medical Benefit - 12 months

Commercial - 6 months or to the member's renewal date, whichever is longer

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents.

IV. 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	<i>Adjuvant therapy for early breast cancer with residual disease</i> 3.6 mg/kg IV Q3WK (21-day cycle) for a total of 14 cycles unless there is disease recurrence or unmanageable toxicity.	3.6 mg/kg
	<i>Metastatic breast cancer</i> 3.6 mg/kg IV Q3WK (21-day cycle) until disease progression or unmanageable toxicity.	

VI. Product Availability

Single-use vial: 100 mg, 160 mg

VII. References

1. Kadcyla Prescribing Information. South San Francisco, CA: Genentech, Inc.; May 2019. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process>. Accessed May 21, 2019.
2. Ado-trastuzumab emtansine. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 21, 2019.
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	P&T Approval Date
Policy split from CP.PHAR.67.HER2 BrCa Tx and converted to new template. Requests for documentation removed. Definition of adjuvant therapy added to criteria per NCI definition. NCCN compendial recommended uses added.	05.16	06.16
Added max dosing criteria.Re-auth: Removed reasons to discontinue. Added requirement for documentation of positive response to therapy. Increased approval durations from 3/6 months to 6/12 months.	04.17	06.17
2Q 2018 annual review; policies combined for Commercial, HIM-Medical Benefit and Medicaid; age, and COC added; 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	05.18
2Q 2019 annual review: expanded COC to all covered indications from just breast cancer; references reviewed and updated.	02.05.19	05.19
Criteria added for new FDA indication: adjuvant therapy in early breast cancer with residual disease; references reviewed and updated.	06.11.19	08.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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