

Clinical Policy: Ado-Trastuzumab Emtansine (Kadcyla)

Reference Number: LA.PHAR.229

Effective Date: 11.03.23

Last Review Date: 05.09.25

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

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

****Please note: This policy is for medical benefit****

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:
 - o Received prior therapy for metastatic disease, or
 - o 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 Louisiana Healthcare Connections 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;
5. One of the following (a or b):
 - a. Documentation of prior use of trastuzumab-based therapy and a taxane;
 - b. Kadcyla prescribed as adjuvant treatment;
6. Request meets one of the following (a, b, or c):*
 - a. As adjuvant treatment: Dose does not exceed 3.6 mg/kg every 21 days for a maximum of 14 doses;
 - b. For metastatic treatment: 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Additional NCCN Recommended Uses (off-label) (must meet all):

1. Diagnosis of one of the following (a or b):
 - a. Recurrent, advanced, or metastatic HER2-positive non-small cell lung cancer (NSCLC);
 - b. Recurrent HER2-positive salivary gland tumor;
2. Prescribed by or in consultation with an oncologist;
3. Age $\geq$ 18 years;
4. Prescribed as a single agent;
5. 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Kadcyra 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, b, or c):*
 - a. As adjuvant treatment 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

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 LA.PMN.53

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. <i>Metastatic breast cancer</i> 3.6 mg/kg IV Q3WK (21-day cycle) until disease progression or unmanageable toxicity.	3.6 mg/kg

VI. Product Availability

Single-use vials: 100 mg, 160 mg

VII. References

1. Kadcylla Prescribing Information. South San Francisco, CA: Genentech, Inc.; July 2024. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=23f3c1f4-0fc8-4804-a9e3-04cf25dd302e> Accessed January 13, 2025.
2. Ado-trastuzumab emtansine. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 27, 2025.
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.
4. National Comprehensive Cancer Network Guidelines. Breast Cancer Version 6.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 27, 2025.

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	LDH Approval Date
Converted corporate to local policy.	04.22	06.08.22

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Template changes applied to other diagnoses/indications. Clarified for NSCLC that disease is recurrent, advanced, or metastatic per NCCN; references reviewed and updated. Added verbiage this policy is for medical benefit only.	06.02.23	10.05.23
Annual review: no significant changes; references reviewed and updated.	06.11.24	09.04.24
Annual review: added bypass of prior use of trastuzumab-based therapy and a taxane if prescribed in the adjuvant setting per NCCN; references reviewed and updated	05.09.25	

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. LHCC 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.

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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.

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