Evolent Clinical Guideline 3011 for Kadcyla™ (ado-trastuzumab emtansine)

Guideline Number:	Applicable Codes	
Evolent_CG_3011		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
April 2013	February 2026	February 2026

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STATEMENT

Purpose

To define and describe the accepted indications for Kadcyla (ado-trastuzumab emtansine) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

HER-2 Positive Breast Cancer

- For recurrent/metastatic HER-2 positive breast cancer: Kadcyla (ado-trastuzumab emtansine) may be used as a single agent for members who have experienced disease progression after prior therapy with [trastuzumab + pertuzumab] +/- chemotherapy, e.g., a taxane.
- For adjuvant therapy of members with stages I-III HER-2 positive breast cancer: Kadcyla (ado-trastuzumab emtansine) may be used as a single agent in members with stage I-III HER-2 positive breast cancer, who have undergone neoadjuvant chemotherapy (taxane and trastuzumab-based treatment) and were found to have residual disease in the breast and/or axillary nodes after surgery.

CONTRAINDICATIONS/WARNINGS

- US Boxed Warning
    - Serious hepatotoxicity has been reported, including liver failure and death in patients treated with ado-trastuzumab emtansine. Monitor serum transaminases and bilirubin prior to initiation of ado-trastuzumab emtansine treatment and prior to each ado-trastuzumab emtansine dose. Reduce the dose or discontinue ado-trastuzumab emtansine as appropriate in cases of increased serum

transaminases or total bilirubin.

- Ado-trastuzumab emtansine administration may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate left ventricular function in all patients prior to and during treatment with ado-trastuzumab emtansine. Withhold treatment for a clinically significant decrease in left ventricular function.
- Exposure to ado-trastuzumab emtansine during pregnancy can result in embryo-fetal harm. Advise patients of these risks and the need for effective contraception.

EXCLUSION CRITERIA

- Concurrent use with trastuzumab, lapatinib, pertuzumab, fam-trastuzumab deruxtecan-nxki, or other chemotherapy; endocrine therapy may continue concurrently with Kadcyla if indicated.
- Disease progression while taking Kadcyla (ado-trastuzumab emtansine).
- Dosing exceeds single dose limit of Kadcyla (ado-trastuzumab emtansine) 3.6 mg/kg.
- Dosing exceeds maximum duration of 14 cycles for adjuvant (curative-intent) treatment.
- Investigational use of Kadcyla (ado-trastuzumab emtansine) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9354 - Injection, ado-trastuzumab emtansine, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
February 2026	• Updated contraindications/warnings section • Updated references
February 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1238 Kadcyla (ado-trastuzumab emtansine)
February 2024	• Updated NCH verbiage to Evolent • Updated "continuation request" verbiage

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent

uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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