

Ado-trastuzumab emtansine (Kadcyla®)

Place of Service
Office Administration
Outpatient Facility
Administration
Infusion Center Administration

HCPCS: J9354 per 1mg

Condition listed in policy (see criteria for details)

- [Breast cancer \(HER2-positive\)](#)
- [Head and neck cancer, salivary gland tumors \(HER2-positive\)](#)
- [Non-small cell lung cancer \(HER2-mutant\)](#)

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: HER2-targeted antibody-drug conjugate consisting of the humanized anti-HER2 antibody, trastuzumab and DM1, a microtubule inhibitor

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Kadcyla® (ado-trastuzumab emtansine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer (HER2-positive)

1. HER2-positivity, **AND**
2. Being used as a single agent, **AND**
3. Meets one of the following:
 - a. Adjuvant systemic therapy following completion of preoperative therapy, **OR**
 - b. Metastatic or recurrent unresectable disease, and patient has received prior trastuzumab therapy

Covered Doses and Coverage Period

Adjuvant treatment:

Up to 3.6 mg/kg IV every 3 wks for up to 17 cycles (17 doses)

Metastatic or recurrent disease:

Up to 3.6 mg/kg IV every 3 wks indefinitely

ICD-10:

C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, Z85.3

Head and neck cancer, salivary gland tumors

1. Diagnosis of salivary gland tumor, **AND**
2. Recurrent, unresectable, or metastatic disease, **AND**
3. HER2-positivity, **AND**
4. Being used as a single agent

Covered Doses

Up to 3.6 mg/kg IV every 3 wks

Coverage Period

Indefinitely

ICD-10:

C06.9, C07, C08.0, C08.1, C08.9

Non-small cell lung cancer (HER2-mutant)

1. Recurrent, advanced, or metastatic disease, **AND**
2. Patient has an ERBB2 (HER2) mutation, **AND**
3. Being used as single agent, **AND**
4. **Effective 10/30/2023 and after**, will require use as subsequent therapy

Covered Doses

PHP Medi-Cal

Ado-trastuzumab emtansine (Kadcyla®)

Up to 3.6 mg/kg IV every 3 wks

Coverage Period

Indefinitely

ICD-10:

C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.118

(3) The following condition(s) **DO NOT** require Prior Authorization/Preservice

All requests for Kadcyła® (ado-trastuzumab emtansine) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied

- 100 mg (single-use vial)
- 160 mg (single-use vial)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Kadcyła® (ado-trastuzumab emtansine) [Prescribing Information]. South San Francisco, CA: Genentech, Inc. 2/2022.
- National Comprehensive Cancer Network. Breast Cancer (Version 4.2023). Available at www.nccn.org.
- National Comprehensive Cancer Network. Head and Neck Cancers (Version 2.2023). Available at www.nccn.org.
- National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 3.2023). Available at www.nccn.org.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- Section (2): Non-small cell lung cancer –
 - Expand coverage of NSCLC to include recurrent and advanced disease
 - Effective 10/30/2023 and after, will require use as subsequent therapy

Rationale: NCCN category 2A support

BSC Drug Coverage Criteria to Determine Medical Necessity

Reviewed by P&T Committee