

Kadcyla (Ado-Trastuzumab Emtansine)

Effective Date: 12/1/2022

Revision Date(s): n/a

Review Date: 10/19/2022

Policy type: Medical Necessity

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Initial Approval Criteria

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

- The member's tumor is human epidermal growth factor receptor 2 (HER2) positive¹, unless otherwise specified.
- Used as a single agent.
- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

Indication Specific Criteria

Breast Cancer

- Member has brain metastases; OR
- Used as adjuvant therapy; OR
- Member has recurrent, unresectable, or stage IV disease; AND
 - Used as subsequent therapy

Head and Neck Cancers

- Member has recurrent disease

Non-Small Cell Lung Cancer (NSCLC)

- Member has recurrent, advanced, or metastatic disease; AND
- Used as subsequent therapy

¹ Per American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guidelines (Focused Update 2018).

Billing

Drug Name	HCPCS Code	Description
Kadcyla	J9354	Inj., ado-trastuzumab emtansine, 1 mg

References

1. Kadcyla. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 9/9/2022
2. Kadcyla [package insert]. Genentech, Inc., South San Francisco, CA. Available at: https://www.gene.com/download/pdf/kadcyla_prescribing.pdf
3. Breast Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed 9/9/22
4. Central Nervous System Cancers: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed 9/9/22
5. Head and Neck Cancers: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed 9/9/22
6. Non-Small Cell Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed 9/9/22

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.