Kadcyla (ado-trastuzumab emtansine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Kadcyla (ado-trastuzumab emtansine)

APPROVAL CRITERIA

Requests for Kadcyla (ado-trastuzumab emtansine) may be approved if the following criteria are met:

I. Individual has a diagnosis of HER2-positive (HER2+) breast cancer (NCCN 1) confirmed by one of the following:
   A. Immunohistochemistry (IHC) is 3 +;
      OR
   B. In situ hybridization (ISH) positive;
   AND
   C. Used in one of the following ways:
      1. Individual has early breast cancer; **AND**
         a. Individual is using as a single agent; **AND**
         b. Individual is using as adjuvant treatment of early non-metastatic breast cancer for residual invasive disease in the breast or axilla after surgery after receiving at least 6 cycles (16 weeks) of neoadjuvant therapy containing a taxane (with or without anthracycline) and trastuzumab (or its biosimilars);

      OR
      2. Individual has metastatic breast cancer disease (DP B IIa); **AND**
         a. Individual is using as a single agent; **AND**
         b. Individual has previously received trastuzumab (or its biosimilars) and a taxane, separately or in combination; **AND**
         c. Individual has either received prior therapy for metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy;
      OR
      3. Individual has recurrent unresectable or metastatic breast cancer (NCCN 2A); **AND**
         a. Individual is using in one of the following ways:
            i. Individual is using as third-line therapy and beyond; **OR**
            ii. Individual is using as second-line if not a candidate for fam-trastuzumab deruxtecan; **AND**
         b. Individual is one of the following:
            i. Individual is hormone receptor-negative; **OR**

ii. Individual is hormone receptor-positive with or without endocrine therapy;

OR

II. Individual has a diagnosis of limited or extensive brain metastases with HER2-positive breast cancer; **AND**
   A. Individual is using as a single agent; **AND**
   B. Using as initial or primary treatment in asymptomatic disease; **OR**
   C. As treatment for recurrent/relapsed disease with stable systemic disease or reasonable systemic treatment options;

OR

III. Individual has a diagnosis of ERBB2 (HER2) mutation positive recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) (NCCN 2A, DP B IIa); **AND**
   A. Individual is using as a single-agent; **AND**
   B. Individual is using as subsequent therapy;

OR

IV. Individual has a diagnosis of recurrent HER2+ salivary gland tumors (NCCN 2A); **AND**
   A. Individual has had prior anti-HER2+ therapy (e.g. trastuzumab or traztuzumab biosimilars) (Clinical judgement); **AND**
   B. Using as single-agent systemic therapy.

Requests for Kadcyla (ado-trastuzumab) may not be approved for the following:

I. When Kadcyla (ado-trastuzumab emtansine) is used in combination with other targeted biologic agents or chemotherapy agents; **OR**
II. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Iwama E, Zenke Y, Sugawara S, et al. Trastuzumab emtansine for patients with non-small cell lung cancer positive for human epidermal growth factor receptor 2 exon-20 insertion mutations. Eur J Cancer 2022;162:99-106. Available at: https://www.ncbi.nlm.nih.gov/pubmed/34959152.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. Li BT, Shen R, Buonocore D, et al. Ado-trastuzumab emtansine in patients with HER2 mutant lung cancers. Results from a phase II basket trial. J.Clin Oncol 2018:36:2532-2537.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 17, 2024..
    a. Breast Cancer. V5.2023. Revised December 5, 2023.
    b. Central Nervous System Cancer. V1.2023. Revised March 24, 2023.
    c. Head and Neck Cancers. V2.2024. Revised December 8, 2023.
    d. Non-Small Cell Lung Cancer. V1.2024. Revised December 21, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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