Ado-trastuzumab emtansine (KADCYLA)
Criteria for Use
February 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ado-trastuzumab emtansine.

- ☐ Known hypersensitivity to ado-trastuzumab emtansine or its excipients (sodium succinate, sucrose, polysorbate 20)
- ☐ Baseline Left Ventricular Ejection Fraction (LVEF) < 50%
- ☐ Uncontrolled hypertension or arrhythmia requiring treatment
- ☐ Myocardial infarction within prior 6 months
- ☐ History of Congestive Heart Failure (New York Heart Association Class 3 or 4)
- ☐ Cumulative prior anthracycline exposure > 360 mg/m2 of doxorubicin or its equivalent
- ☐ Breast tissue does not overexpress HER2 protein (HER2 positive status defined as IHC 3+ or FISH amplification ratio > 2.0)
- ☐ Platelet count < 100,000/ mm^3
- ☐ Grade 3 or higher peripheral neuropathy
- ☐ Serum transaminases (ALT/AST) > 2.5x ULN and/or Total bilirubin > 1.5x ULN or active hepatitis B or C virus
- ☐ Interstitial Lung Disease or pneumonitis

Inclusion Criteria *One of the following criteria must be met*

- ☐ In metastatic setting, patient received prior treatment for metastatic breast cancer that includes trastuzumab and taxane (separately or in combo) or disease recurred during or within 6 months of completing adjuvant therapy
- ☐ As adjuvant therapy, in patient with early breast cancer with residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment

Additional Inclusion Criteria *The answers to the following must be fulfilled*

- ☐ Care for the condition provided by VA or VA Community Care oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Eastern Cooperative Oncology Group Performance Status 0-2

Additional Inclusion Criteria *Select if applicable*

- ☐ For patients who can become pregnant: Pregnancy should be excluded prior to receiving ado-trastuzumab emtansine
- ☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 7 months after stopping treatment
- ☐ For patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 4 months after stopping treatment

Other Justification

- ☐ _____

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