Genentech | ACCESS SOLUTIONS®
A Member of the Roche Group

for Kadcyla®
(ado-trastuzumab emtansine)

SAMPLE CODING

Breast Cancer

TYPE	CODE		DESCRIPTION
Diagnosis: ICD-10-CM	C50.011–C50.019 C50.111–C50.119 C50.211–C50.219 C50.311–C50.319 C50.411–C50.419 C50.511–C50.519 C50.611–C50.619 C50.811–C50.819 C50.911–C50.919		Malignant neoplasm of the female breast
	C50.021–C50.029 C50.121–C50.129 C50.221–C50.229 C50.321–C50.329 C50.421–C50.429 C50.521–C50.529 C50.621–C50.629 C50.821–C50.829 C50.921–C50.929		Malignant neoplasm of the male breast
Drug: HCPCS	J9354		Injection, ado-trastuzumab emtansine, 1 mg
Drug: NDC Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	10-digit	11-digit	
	50242-088-01	50242-0088-01	100-mg single-dose vial
	50242-087-01	50242-0087-01	160-mg single-dose vial
Administration procedures: CPT	96413		Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415		Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
Hospital revenue codes:	0636		Drugs requiring detailed coding
	0250		Pharmacy
	0260		IV therapy

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

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INDICATIONS & IMPORTANT SAFETY INFORMATION

Indications

Metastatic Breast Cancer (MBC)

KADCYLA, as a single agent, is indicated for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.

Select patients for therapy based on an FDA-approved companion diagnostic for KADCYLA.

Early Breast Cancer (EBC)

KADCYLA, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.

Select patients for therapy based on an FDA-approved companion diagnostic for KADCYLA.

Important Safety Information

BOXED WARNINGS: HEPATOTOXICITY, CARDIAC TOXICITY, EMBRYO-FETAL TOXICITY

- **Hepatotoxicity: Serious hepatotoxicity has been reported, including liver failure and death in patients treated with KADCYLA. Monitor serum transaminases and bilirubin prior to initiation of KADCYLA treatment and prior to each KADCYLA dose. Reduce dose or discontinue KADCYLA as appropriate in cases of increased serum transaminases or total bilirubin**
- **Cardiac Toxicity: KADCYLA administration may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate left ventricular function in all patients prior to and during treatment with KADCYLA. Withhold treatment for clinically significant decrease in left ventricular function**
- **Embryo-Fetal Toxicity: Exposure to KADCYLA can result in embryo-fetal death or birth defects. Advise patients of these risks and the need for effective contraception**

Additional Important Safety Information

- Interstitial lung disease (ILD), including pneumonitis, some leading to acute respiratory distress syndrome or fatality: Permanently discontinue KADCYLA in patients diagnosed with ILD or pneumonitis
- Infusion-related reactions (IRR), hypersensitivity: KADCYLA treatment should be interrupted in patients with severe IRR and permanently discontinued in the event of a life-threatening IRR
- Hemorrhage: Fatal cases of hemorrhage occurred in clinical trials among patients with no known identified risk factors, as well as among patients with thrombocytopenia and those receiving anticoagulation and antiplatelet therapy. Use caution with these agents and consider additional monitoring when concomitant use is medically necessary
- Thrombocytopenia: Monitor platelet counts prior to initiation of KADCYLA and prior to each dose. Institute dose modifications as appropriate
- Peripheral neuropathy: Temporarily discontinue KADCYLA in patients experiencing Grade 3 or 4 peripheral neuropathy until resolution to ≤ Grade 2
- Reactions secondary to extravasation: Closely monitor the infusion site for possible subcutaneous infiltration during drug administration
- In metastatic breast cancer, the most common adverse reactions (≥25%) with KADCYLA were fatigue, nausea, musculoskeletal pain, hemorrhage, thrombocytopenia, headache, increased transaminases, constipation and epistaxis
- In early breast cancer, the most common adverse reactions seen with KADCYLA in the KATHERINE trial (frequency >25%) were fatigue, nausea, increased transaminases, musculoskeletal pain, hemorrhage, thrombocytopenia, headache, peripheral neuropathy, and arthralgia
- Advise women not to breastfeed during treatment and for 7 months following the last dose of KADCYLA

You are encouraged to report side effects to Genentech and the FDA. You may contact Genentech by calling 1-888-835-2555. You may contact the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Please click here for additional Important Safety Information and accompanying full Prescribing Information, including BOXED WARNINGS.

Please see accompanying full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.