

for **Herceptin**®
(trastuzumab)

SAMPLE CODING

Metastatic Gastric Cancer

TYPE	CODE		DESCRIPTION
Diagnosis: ICD-10-CM	C16.0–C16.9		Malignant neoplasm of the stomach
Drug: HCPCS	J9355		Injection, trastuzumab, 10 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	
	50242-132-01	50242-0132-01	150 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
	96417		Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour

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.

INDICATIONS & IMPORTANT SAFETY INFORMATION

Indications

Adjuvant Breast Cancer

Herceptin is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature*) breast cancer:

- As part of a treatment regimen containing doxorubicin, cyclophosphamide and either paclitaxel or docetaxel
- With docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

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

*High-risk is defined as ER/PR-positive with one of the following features: tumor size >2 cm, age <35 years, or tumor grade 2 or 3.

Metastatic Breast Cancer

Herceptin is indicated:

- In combination with paclitaxel for the first line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

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

Please see additional select Important Safety Information throughout, and the accompanying full Prescribing Information, including Boxed WARNINGS.

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Important Safety Information

Indications (cont)

Metastatic Gastric Cancer

Herceptin is indicated, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.

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

Boxed WARNINGS and Additional Important Safety Information

Cardiomyopathy

- Herceptin administration can result in sub-clinical and clinical cardiac failure. The incidence and severity was highest in patients receiving Herceptin with anthracycline-containing chemotherapy regimens.
- Evaluate left ventricular function in all patients prior to and during treatment with Herceptin. Discontinue Herceptin treatment in patients receiving adjuvant therapy and withhold Herceptin in patients with metastatic disease for clinically significant decrease in left ventricular function

Infusion Reactions; Pulmonary Toxicity

- Herceptin administration can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of Herceptin administration. Interrupt Herceptin infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue Herceptin for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome

Embryo-Fetal Toxicity

- Exposure to Herceptin during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception
- Exacerbation of chemotherapy-induced neutropenia has also occurred
- The most common adverse reactions associated with Herceptin in breast cancer were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia
- The most common adverse reactions associated with Herceptin in metastatic gastric cancer were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Please see additional select Important Safety Information throughout, and the accompanying [full Prescribing Information](#), including **Boxed WARNINGS**.

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