Genentech | ACCESS SOLUTIONS®
A Member of the Roche Group

for Herceptin HYLECTA™
(trastuzumab and hyaluronidase-oysk)

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	J9356		Injection, trastuzumab 10 mg and hyaluronidase-oysk
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	
	50242-077-01	50242-0077-01	600 mg/10,000 units
Administration procedures: CPT	96401		Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

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 HYLECTA (trastuzumab and hyaluronidase-oysk) is indicated for adjuvant treatment of adults with 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

Please see the HERCEPTIN HYLECTA full Prescribing Information for additional Important Safety Information including BOXED WARNINGS.

for Herceptin HYLECTA™
(trastuzumab and hyaluronidase-oysk)

Indications (cont)

Adjuvant Breast Cancer (cont)

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

*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 HYLECTA is indicated in adults:

- 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 trastuzumab

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS and Additional Important Safety Information

Cardiomyopathy

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

Pulmonary Toxicity

- **HERCEPTIN HYLECTA administration can result in serious fatal pulmonary toxicity. Symptoms usually occur during or within 24 hours of HERCEPTIN HYLECTA administration. Discontinue HERCEPTIN HYLECTA for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Monitor patients until symptoms completely resolve**

Embryo-Fetal Toxicity

- **Exposure to HERCEPTIN HYLECTA 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
- Hypersensitivity and severe Administration-Related Reactions (ARRs) including anaphylaxis, have been reported with HERCEPTIN HYLECTA. Serious and fatal reactions have been reported after treatment with intravenous trastuzumab products

Most Common Adverse Reactions

- **Adjuvant Breast Cancer:** Most common adverse reactions for HERCEPTIN HYLECTA are fatigue, arthralgia, diarrhea, injection site reaction, upper respiratory tract infection, rash, myalgia, nausea, headache, edema, flushing, pyrexia, cough, and pain in extremity.
- **Metastatic Breast Cancer (based on intravenous trastuzumab):** The most common adverse reactions are fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash.

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.

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