



Trastuzumab (Herceptin®)

Revision: 2

Policy Number: M-0005

Last Update: 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

When appropriate compendia references the use of one of the chemotherapeutic agents listed in this Article as part of a 'combination therapy', the drug is only approved for use in such 'combinations', and the documentation should reflect, and be specific about, the use of the additional 'combination therapy' drugs.

Coverage Guidelines:

FDA:

1. The treatment of HER2 overexpressing breast cancer
2. The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma

Off Label:

1. Breast cancer, Neoadjuvant, HER2 overexpression, in combination with chemotherapy
2. Metastatic breast cancer, HER2 overexpression, monotherapy
3. Metastatic breast cancer, HER2 over expression, in combination with chemotherapy

Coding Information:

HCPCS Code(s)

J9355	INJECTION, TRASTUZUMAB, 10 MG
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ICD-9 Code(s)

150.0-	MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT
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150.5	NEOPLASM OF LOWER THIRD OF ESOPHAGUS
150.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED PART OF ESOPHAGUS
150.9	MALIGNANT NEOPLASM OF ESOPHAGUS UNSPECIFIED SITE
151.0-151.6	MALIGNANT NEOPLASM OF CARDIA - MALIGNANT NEOPLASM OF GREATER CURVATURE OF STOMACH UNSPECIFIED
151.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF STOMACH
151.9	MALIGNANT NEOPLASM OF STOMACH UNSPECIFIED SITE
174.0-174.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0-175.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
198.2	SECONDARY MALIGNANT NEOPLASM OF SKIN
198.81	SECONDARY MALIGNANT NEOPLASM OF BREAST
235.2	NEOPLASM OF UNCERTAIN BEHAVIOR OF STOMACH INTESTINES AND RECTUM
235.5	NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER AND UNSPECIFIED DIGESTIVE ORGANS

Background:

Herceptin (trastuzumab) is a humanized IgG1 kappa monoclonal antibody that selectively binds with high affinity to the extracellular domain of the human epidermal growth factor receptor 2 protein, HER2.

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.



FDA Black Box Warning:

WARNING: CARDIOMYOPATHY, INFUSION REACTIONS, EMBRYO-FETAL TOXICITY, and PULMONARY TOXICITY

Cardiomyopathy

Herceptin administration can result in sub clinical and clinical cardiac failure. The incidence and severity was highest in patients receiving Herceptin with anthracyclinecontaining 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.

References:

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; October 2010. Available at: <http://www.gene.com/gene/products/information/pdf/herceptin-prescribing.pdf>. Accessed May 21, 2012.



2. The NCCN Drugs & Biologics Compendium™ © 2010 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 21, 2012.
3. Local Coverage Article for Drugs and Biologicals – Chemotherapeutic Agents (A48896) (R4). Available at: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48896&ver=89&ContrId=213&ContrVer=1&CtrctrSelected=213*1&Date=01%2f01%2f2013&DocID=A48896&bc=hAAAAAaAEAAAAA%3d%3d&. Accessed June 4, 2014.
4. Micromedex®2.0-Trastuzumab. Available at: http://www.thomsonhc.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/D4B0C7/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/DA4DF1/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=924802&contentSetId=100&title=Trastuzumab&servicesTitle=Trastuzumab&topicId=dosingAndIndicationsSection&subtopicId=nonfdaSection. Accessed May 21, 2012.

Document History:

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