Pertuzumab (Perjeta®) **Policy Number: M-0048**
Revision: 2 **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.

Coverage Guidelines:

FDA

- Treatment of patients with HER2-positive metastatic breast cancer in combination with trastuzumab and docetaxel who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Coding Information:

HCPCS Code(s)

J3590†	Unclassified biologics
J3490†	Unclassified drugs
J9999†	Not otherwise classified, antineoplastic drugs

†—unclassified codes must be submitted with an appropriate NDC for payment consideration

ICD-9 Code(s)

174.0 – 174.9	Malignant neoplasm of female breast
175.0 - 175.9	Malignant neoplasm of male breast

Limitations:

Perjeta is supplied as a 420mg/14 mL (30mg/mL) single-use vial containing preservative free solutions. As approved by the FDA, the recommended initial dosage regimen for Perjeta is 840mg administered as a 60-minute intravenous infusion, followed every 3 weeks thereafter by a dose of 420 mg administered as an intravenous infusion over 30 to 60 minutes.

When administered with Perjeta, the recommended initial dose of trastuzumab is 8 mg/kg administered as a 90-minute intravenous infusion, followed every 3 weeks thereafter by a dose of 6 mg/kg administered as an intravenous infusion over 30 to 90 minutes.

When administered with Perjeta, the recommended initial dose of docetaxel is 75 mg/m^2 administered as an intravenous infusion. The dose may be escalated to 100 mg/m^2 administered every 3 weeks if the initial dose is well tolerated.

Black Box Warning:

WARNING: EMBRYO-FETAL TOXICITY

Exposure to pertuzumab can result in embryo-fetal death and birth defects. Advise patients of these risks and the need for effective contraception.

Background:

Perjeta (pertuzumab) is a HER2/neu receptor antagonist indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease

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.

$HER2^+$—Human epidermal growth factor Receptor 2 positive

References:

1. Perjeta [Package Insert]. South San Francisco, CA: Genentech, Inc.; 2012. Available at: http://www.gene.com/gene/products/information/perjeta/pdf/perjeta_prescribing.pdf. Accessed June 4, 2014.
2. Perjeta Micromedex. Available at: http://www.thomsonhc.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/CA2100/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/6A7618/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=930221&contentSetId=100&title=Pertuzumab&servicesTitle=Pertuzumab&topicId=blackBoxWarningSection&subtopicId=null. Accessed December 5, 2013.
3. Perjeta Clinical Pharmacology. Available at: https://www.clinicalpharmacology.com/Forms/Monograph/monograph.aspx?cpnum=3768&sec=monindi&t=0. Accessed June 4, 2014.

Document History:

Date Written: 11/29/12
Effective Date: 1/1/13
Revision 1: 12/5/13
Revision 2: 6/4/2014
Internal Review: 6/11/2014
External Review: 6/17/2014

For the Archived Policy, please go to http://www.vivaprovider.com/Resources/CoveragePolicies.aspx and click on the Archived Policies Link.