CLINICAL MEDICATION POLICY	
Policy Name:	Perjeta® (pertuzumab)
Policy Number:	MP-011-MC-ALL
Responsible Departments:	Medical Management, Medical Policy, Clinical Pharmacy
Provider Notice Date:	04/1/2017
Original Effective Date:	05/01/2017
Annual Approval Date:	03/15/2018
Revision Date:	N/A
Products:	Ohio Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
Page Number(s):	1 of 6

Disclaimer

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ may provide coverage under the medical or pharmacy benefits of the Company's Medicare products for medically necessary intravenous infusion of Perjeta (pertuzumab).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

DEFINITIONS

Perjeta (pertuzumab) – A monoclonal antibody used in the treatment of HER2-positive metastatic breast cancer, locally advanced breast cancer, and early stage breast cancer. The antibody prevents growth of cancer cells via its blockade of HER2 receptors.

Left Ventricular Ejection Fraction (LVEF) – The fraction of outbound blood pumped from the heart with each heartbeat. It is commonly measured by an echocardiogram and serves as a general measure of a person's cardiac function. A normal LVEF is 50% to 75%. A decreased LVEF is a result of cardiomyopathy, cardiac arrest, and heart failure.

Taxane – A class of anticancer drugs that inhibit the division of tumor cells by binding to and interfering with the action of microtubules (e.g., paclitaxel and docetaxel).

Neoadjuvant therapy – The administration of therapeutic agents before a main treatment.

HER2 overexpression (human epidermal growth factor receptor 2) – A gene that can play a role in the development of breast cancer. A HER2 gene makes HER2 proteins, which are receptors on the breast cells. Normally, HER2 helps to control healthy breast cell growth and repair. Within 25% of breast cancers, the HER2 does not work correctly and makes too many copies of itself, which in turn create too many HER2 receptors (protein overexpression).

PROCEDURES

1. Perjeta (pertuzumab) is considered medically necessary as an intravenous infusion for:

    A. The treatment of metastatic breast cancer when the patient meets the following criteria:
        1) The patient is aged 18 years or older; AND
        2) The prescribing physician must be a hematologist or oncologist; AND
        3) The patient is not pregnant; AND
        4) The patient has HER2 overexpressing metastatic disease; AND
        5) The patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease; AND
        6) The drug is used in combination with trastuzumab and a taxane; AND
        7) Left ventricular must be assessed prior to and during Perjeta treatment with a left ventricular ejection fraction (LVEF) ≥ 50%.

    B. Neoadjuvant treatment of breast cancer when the patient meets the following criteria:
        1) The patient is aged 18 years or older; AND
        2) The prescribing physician must be a hematologist or oncologist; AND
        3) The patient is not pregnant; AND
        4) The patient has HER2 overexpressing breast cancer; AND
        5) The patient has locally advanced, inflammatory, or operable early stage breast cancer (either greater than 2 cm in diameter or node positive) ; AND
        6) The drug is used preoperatively prior to resection of the breast tumor; AND

7) The drug is used in combination with trastuzumab and a taxane; AND
8) The patient must express pathological complete response rate improvement; AND
9) Left ventricular must be assessed prior to and during Perjeta treatment with a left ventricular ejection fraction (LVEF) ≥ 50%; AND
10) Perjeta may only be used for a maximum of 6 cycles or 18 weeks; AND
11) Dosing is consistent with FDA-approved labeling:
    a. 840 mg IV for the first dose
    b. 420 mg IV every 3 weeks for maintenance
    c. A total treatment duration of 6 cycles (18 weeks)

2. Contraindications
   Perjeta is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its excipients.

   Exposure to Perjeta can result in embryo-fetal death and birth defects. Patients must be advised of the risks and the need for effective contraception.

3. When Perjeta is not covered
   Perjeta is not covered for conditions other than those listed above because the scientific evidence has not been established.

   Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case-by-case basis to determine medical necessity.

   When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the administration of Perjeta is outpatient.

6. Coverage Determination
   Gateway Health℠ follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

There is no specific NCD for this medication. For Ohio, CGS, the local carrier, does not have a specific LCD for Perjeta. For additional information, please see: http://www.cgsmedicare.com/partb/medicalpolicy/index.html.

Governing Bodies Approval

On June 8, 2012, Perjeta was first approved by the FDA for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2+ metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

On October 1, 2013, the FDA approved Perjeta for certain women with early stage breast cancer before surgery.

CODING REQUIREMENTS

Procedure Codes

CPT/HCPCS Codes	Description
J9306	Injection, pertuzumab, 1 mg

Diagnosis Codes

ICD-10 Code	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast

C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C79.81	Secondary malignant neoplasm of breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
Z85.3	Personal history of malignant neoplasm of breast

REMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S)

Perjeta® (Pertuzumab) [package insert]. San Francisco, CA: Genentech; 2017. Accessed on 01/05/2017 and available at: http://www.perjeta.com/.

National Comprehensive Cancer Network® NCCN Clinical Practice Guidelines in Oncology™. Accessed on January 3, 2017 and available at: http://www.nccn.org/index.asp.

- NCCN Guidelines Version 2.2016: Breast Cancer

Pertuzumab. In: Micromedex 2.0 online. Ann Arbor, MI. Truven Health Analytics; 2016. Accessed on August 12, 2016.

Pertuzumab. In: Lexicomp Online®, Lexi-Interact, Hudson, Ohio: Lexi-Comp, Inc.; 2016. Accessed on August 12, 2016.

Policy History:

Date	Activity
N/A	LCD/NCD effective date
03/15/2017	QI/UM Committee approval
05/01/2017	Provider effective date