MetroPlus Health Plan

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ANTINEOPLASTIC AGENT/MONOCLONAL ANTIBODY**
BRAND NAME/(generic)	**PERJETA (pertuzumab)**
Type: Initial Prior Authorization	

Effective Date:
Review Date: 11/18/19

FDA-APPROVED INDICATIONS/COMPENDIAL USES

FDA-Approved Indications[1]

1. Metastatic breast cancer
   In combination with trastuzumab and docetaxel for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

2. Neoadjuvant treatment of breast cancer
   In combination with trastuzumab and chemotherapy as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.

3. Adjuvant treatment of breast cancer
   In combination with trastuzumab and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.

Compendial Uses[2,3]

1. Treatment of recurrent HER2-positive breast cancer

All other indications are considered experimental/investigational and are not a covered benefit.

MECHANISM OF ACTION

Pertuzumab targets the extracellular dimerization domain (Subdomain II) of the human epidermal growth factor receptor 2 protein (HER2) and, thereby, blocks ligand-dependent heterodimerization of HER2 with other HER family members, including EGFR, HER3 and HER4. As a result, pertuzumab inhibits ligand-initiated intracellular signaling through two major signal pathways, mitogen-activated protein (MAP) kinase and phosphoinositide 3-kinase (PI3K). Inhibition of these signaling pathways can result in cell growth arrest and apoptosis, respectively. In addition, pertuzumab mediates antibody-dependent cell-mediated cytotoxicity (ADCC).

COVERAGE CRITERIA

A. Authorization of 6 months may be granted for neoadjuvant therapy of HER2-positive breast cancer.
B. Authorization of 12 months may be granted for adjuvant therapy of HER2-positive breast cancer and treatment of recurrent or metastatic HER2-positive breast cancer.

AND

- Patient does not have the following contraindication/health condition:
  Known hypersensitivity to Perjeta or any of its excipients

AND

Perjeta dosing is in accordance with the FDA approved dosing schedule:

The initial dose is 840 mg administered as a 60-minute intravenous infusion, followed every 3 weeks thereafter by 420 mg administered as a 30 to 60-minute intravenous infusion

Renewal Request:

- All initial conditions of coverage have been met

AND

- Documented improvement of the condition

AND

- The patient did not experience any adverse effects while on Perjeta therapy:

Approved x 12 months

REFERENCES

1. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; December 2017.
2. The NCCN Drugs & Biologics Compendium™ © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 17, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2017. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf . Accessed January 17, 2018.