MetroPlus Health Plan

PRIOR AUTHORIZATION CRITERIA

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

Effective Date:
Review Date: 11/18/19

FDA-APPROVED INDICATIONS/COMPENDIAL USE

FDA-Approved Indications[1-2]

1. Adjuvant breast cancer
   Treatment of human epidermal growth factor receptor 2 (HER2)-overexpressing node positive or node negative (estrogen receptor (ER)/progesterone receptor (PR) negative or with one high risk feature) breast cancer:
   a. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   b. As part of a treatment regimen with docetaxel and carboplatin
   c. As a single agent following multi-modality anthracycline based therapy
2. Metastatic breast cancer
   a. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
   b. As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease
3. Metastatic gastric or gastroesophageal junction cancer
   In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.

Compendial Uses[3-5]

1. HER2-positive breast cancer
   a. Neoadjuvant therapy
   b. Treatment of recurrent disease
2. Leptomeningeal metastases from HER2-positive breast cancer
3. HER2-positive esophageal and esophagogastric cancer

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

MECHANISM OF ACTION

Trastuzumab consists of two antigen-specific sites that bind to the juxtamembrane portion of the extracellular domain of the HER2 receptor and that prevent the activation of its intracellular tyrosine kinase.2 The remainder of the antibody is human IgG with a conserved Fc portion.

COVERAGE CRITERIA

A. Breast Cancer

1. Authorization of 6 months may be granted for neoadjuvant treatment of HER2-positive breast cancer.
2. Authorization of up to 12 months total may be granted for adjuvant treatment of HER2-positive breast cancer, treatment of HER2-positive metastatic or recurrent breast cancer, treatment of leptomeningeal metastases from HER2-positive breast cancer.

B. Esophageal, Gastric, or Gastroesophageal Junction Cancer

1. Authorization of 12 months may be granted for treatment of HER2-positive esophageal, gastric, or gastroesophageal junction cancer.

AND

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

AND

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

- Adjuvant Treatment of HER2-Overexpressing Breast Cancer
  Administer at either
    a. Initial dose of 4 mg/kg over 90-minute IV infusion, then 2 mg/kg over 30-minute IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel/carboplatin). One week after the last weekly dose of Herceptin, administer 6 mg/kg as an IV infusion over 30 to 90 minutes every three weeks to complete a total of 52 weeks of therapy
    b. Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30 to 90 minutes IV infusion every three weeks for 52 weeks.
- Metastatic HER2-Overexpressing Breast Cancer
    a. Initial dose of 4 mg/kg as a 90-minute IV infusion followed by subsequent weekly doses of 2 mg/kg as 30-minute IV infusions.
- Metastatic HER2-Overexpressing Gastric Cancer
    a. Initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks.

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 Herceptin therapy:

Approved x 12 months

REFERENCES

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; April 2017.
2. Ogivri [package insert]. Zurich, Switzerland: Mylan GmbH; December 2017.
3. The NCCN Drugs & Biologics Compendium™ © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 17, 2018.
4. 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.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: esophageal and esophagogastric junction cancers. Version 4.2017. https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed January 17, 2018