Reference number(s)
1905-A

SPECIALTY GUIDELINE MANAGEMENT

HERCEPTIN (trastuzumab)
OGIVRI (trastuzumab-dkst)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. 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.

B. 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.

II. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer[1-4]
   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.
   3. Authorization of 12 months may be granted for treatment of HER2-positive metastatic or recurrent breast cancer.
   4. Authorization of 12 months may be granted for treatment of leptomeningeal metastases from HER2-positive breast cancer.

B. Esophageal, Gastric, or Gastroesophageal Junction Cancer[1-3,5]
Authorization of 12 months may be granted for treatment of HER2-positive esophageal, gastric, or gastroesophageal junction cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. 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