Reference number(s)
1905-A

SPECIALTY GUIDELINE MANAGEMENT

HERCEPTIN (trastuzumab)
OGIVRI (trastuzumab-dkst)
KANJINTI (trastuzumab-anns)
TRAZIMERA (trastuzumab-qyyp)
HERZUMA (trastuzumab-pkrb)
ONTRUZANT (trastuzumab-dttb)

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. 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 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
1. HER2-positive breast cancer
   a. Neoadjuvant therapy
   b. Treatment of recurrent, advanced unresectable, or stage IV (M1) disease
2. Intra-cerebrospinal fluid (CSF) treatment for leptomeningeal metastases from HER2-positive breast cancer
3. HER2- positive esophageal and esophagogastric junction cancer
4. HER2- positive advanced or recurrent uterine serous carcinoma
5. HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab or lapatinib
6. HER2- positive salivary gland tumor

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status (where applicable), RAS mutation status (where applicable), BRAF mutation status (where applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer

1. Authorization of up to 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.
2. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.
3. Authorization of 12 months may be granted for treatment of HER2-positive recurrent, advanced unresectable, or metastatic (including brain metastases) breast cancer.
4. Authorization of 12 months may be granted for intra-CSF treatment for leptomeningeal metastases from HER2-positive breast cancer.

B. Esophageal, Gastric, or Gastroesophageal Junction Cancer

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

C. Uterine Serous Carcinoma

Authorization of 12 months may be granted for treatment of HER2-positive advanced or recurrent uterine serous carcinoma in combination with carboplatin and paclitaxel.

D. Colorectal Cancer

Authorization of 12 months may be granted for treatment of colorectal cancer with HER2-amplified and RAS and BRAF wild-type disease in combination with pertuzumab or lapatinib when either of the following are met:

1. Member is not appropriate for intensive therapy
2. Trastuzumab will be used as subsequent therapy for progression of advanced or metastatic disease

E. Salivary Gland Tumor

Authorization of 12 months may be granted for treatment of HER2-positive salivary gland tumors .

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

V. REFERENCES

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; November 2018.
2. Kanjinti [package insert]. Thousand Oaks, CA: Amgen, Inc.; October 2019.
3. Ogivri [package insert]. Zurich, Switzerland: Mylan GmbH; June 2020
4. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2019.

5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc. May 2019.
6. Ontruzant [package insert]. Whitehouse Station, NJ: Merck. March 2020.
7. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 4, 2020.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 6.2020. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 6, 2020.
9. Thorpe LM, Schrock AB, Erlich RL, et al. Significant and durable clinical benefit from trastuzumab in 2 patients with HER2-amplified salivary gland cancer and a review of the literature. Head Neck. 2017;39(3): E40-E44.

