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
   Adjuvant 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
   c. Treatment for no response to preoperative systemic therapy
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, recurrent, or metastatic uterine serous carcinoma
5. HER2-amplified/positive and RAS and BRAF wild-type colorectal cancer
6. HER2-positive salivary gland tumor
7. HER2-positive hepatobiliary cancers

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 breast cancer with no response to preoperative systemic therapy, recurrent, advanced, unresectable, or metastatic (including brain metastases) disease.
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 or palliative therapy 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, recurrent, or metastatic uterine serous carcinoma in combination with carboplatin and paclitaxel.

D. Colorectal Cancer

Authorization of 12 months may be granted for treatment of unresectable, advanced, or metastatic colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, when all of the following criteria are met:

1. Member has HER2-positive/amplified disease
2. The disease is negative (wild-type) for RAS (KRAS and NRAS) and BRAF mutations
3. The requested medication will be used in combination with tucatinib, pertuzumab, or lapatinib
4. Member has received prior therapy for the disease or is not appropriate for intensive therapy

E. Salivary Gland Tumor

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

F. Hepatobiliary Cancers

Authorization of 12 months may be granted for subsequent treatment of unresectable or metastatic HER2-positive hepatobiliary cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer) when used in combination with pertuzumab.

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

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7. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 27, 2023.
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