Reference number(s)
2474-A

STANDARD MEDICARE PART B MANAGEMENT

HERCEPTIN (trastuzumab)
KANJINTI (trastuzumab-anns)
OGIVRI (trastuzumab-dkst)
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 or stage IV (M1) disease
2. Intra-cerebrospinal fluid (CSF) treatment of leptomeningeal metastases from breast cancer
3. HER2-positive esophageal and esophagogastric junction cancer
4. HER2- positive advanced and recurrent uterine serous carcinoma
5. HER2-positive recurrent salivary gland tumors with distant metastases
6. HER2-amplified and RAS wild-type colorectal cancer in combination with pertuzumab or lapatinib
7. HER2-positive non-small cell lung cancer
8. Prostate cancer

9. Malignant meningitis

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer

1. Authorization of 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.
2. Authorization of 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 or metastatic breast cancer.
4. Authorization of 12 months may be granted for intra-CSF treatment of leptomeningeal metastases from breast cancer.

B. Esophageal, gastric, or esophagogastric junction cancer

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

C. Uterine serous carcinoma

Authorization of 12 months may be granted for treatment of HER2-positive advanced and recurrent uterine serous carcinoma.

D. Salivary gland tumors

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

E. Colorectal Cancer

Authorization of 12 months may be granted for treatment of HER2-amplified colorectal cancer.

F. Non-small cell lung cancer

Authorization of 12 months may be granted for treatment of HER2-positive non-small cell lung cancer.

G. Prostate cancer

Authorization of 12 months may be granted for treatment of prostate cancer.

H. Malignant meningitis

Authorization of 12 months may be granted for treatment of malignant meningitis

III. CONTINUATION OF THERAPY

Authorization may be granted for all members (including new members) who are continuing with Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant therapy when all of the criteria below are met. Authorization duration will be 6 months for neoadjuvant treatment of breast cancer and 12 months for other settings or conditions.

A. The member is currently receiving treatment with Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant.
B. Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant is being used to treat a diagnosis or condition enumerated in Section II.

C. Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant has been effective for treating the diagnosis or condition.

IV. 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; November 2019.
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. Available at: https://www.nccn.org. Accessed January 6, 2020.
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9. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com. Accessed January 14, 2020.
10. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2020. https://www.clinicalkey.com/pharmacology. Accessed January 14, 2020.
11. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed January 14, 2020.