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
   i. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   ii. As part of a treatment regimen with docetaxel and carboplatin
   iii. As a single agent following multi-modality anthracycline based therapy
2. Metastatic breast cancer
   i. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
   ii. 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:
   i. Neoadjuvant therapy
   ii. Treatment of recurrent, advanced unresectable, or stage IV (M1) disease
2. Intra-cerebrospinal fluid (CSF) treatment of leptomeningeal metastases from HER2-positive breast cancer
3. HER2-positive esophageal and esophagogastric junction cancer
4. HER2- positive advanced, metastatic, or recurrent uterine serous carcinoma
5. HER2-positive salivary gland tumors

6. HER2-amplified and RAS and BRAF 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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Human epidermal growth factor receptor 2 (HER2) status, where applicable
B. RAS mutation status, where applicable
C. BRAF mutation status, where applicable

III. 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, advanced unresectable, or metastatic breast cancer.
4. Authorization of 12 months may be granted for intra-CSF treatment of leptomeningeal metastases from HER2-positive 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, metastatic or recurrent uterine serous carcinoma.

D. Salivary gland tumors

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

E. Colorectal Cancer

Authorization of 12 months may be granted for treatment of HER2-amplified and RAS and BRAF wild-type 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.

IV. CONTINUATION OF THERAPY

Authorization of 12 months 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 12 months total for adjuvant and neoadjuvant treatment of breast cancer.

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 III.
C. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen AND
   ii. No evidence of disease progression while on the current regimen

V. REFERENCES

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
2. Kanjinti [package insert]. Thousand Oaks, CA: Amgen, Inc.; October 2019.
3. Ogivri [package insert]. Zurich, Switzerland: Mylan GmbH; February 2021.
4. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2020.
5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc. May 2019.
6. Ontruzant [package insert]. Whitehouse Station, NJ: Merck. June 2021.
7. The NCCN Drugs & Biologics Compendium® © 2021National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed December 8, 2021.
8. Micromedex Solutions [electronic version]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed December 7, 2021.
9. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com. Accessed December 7, 2021.
10. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2021. https://www.clinicalkey.com/pharmacology. Accessed January 20,2021
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 December 8, 2021.