Trastuzumab (Herceptin®) **Trastuzumab-anns (Kanjinti™)** **Trastuzumab-dkst (Ogivri™)** **Trastuzumab-dttb (Ontruzant ®)** **Trastuzumab-pkrb (Herzuma ®)** **Trastuzumab-qyyp (Trazimera™)**	**Medicare Part B** Blue Shield Medicare (PPO) **HCPCS** Herceptin: J9355 per 10 mg Ontruzant: Q5112 per 10 mg Herzuma: Q5113 per 10 mg Ogivri: Q5114 per 10 mg Trazimera: Q5116 per 10 mg Kanjinti: Q5117 per 10 mg

Special Instructions and Pertinent Information

These drugs are covered when used to treat a medically accepted indication as established by 1) the Centers for Medicare & Medicaid Services (CMS), and 2) step therapy requirement with one of the BSC-preferred drugs, Kanjinti or Trazimera, when applicable.

CMS allows Medicare Advantage (MA) Plans to apply step therapy to physician-administered and other Part B drugs. Blue Shield of California (BSC) requires this drug to be reviewed for step therapy requirements in addition to CMS medical necessity requirements. Step therapy with one of the BSC-preferred drugs, Kanjinti or Trazimera, is required for members newly initiating trastuzumab therapy, when applicable.

Food and Drug Administration (FDA)-Approved Indications for Reference Product

- **Breast cancer (HER2-positive)**
- **Gastric or gastroesophageal junction adenocarcinoma (HER2-positive)**

Coverage Criteria for FDA-Approved Indications

Breast cancer (HER2-positive)

1. Either of the following:
    a. Adjuvant treatment and node positive or node negative (ER/PR negative or with one high risk feature), and one of the following:
        i. Used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, OR
        ii. Used as part of a treatment regimen with docetaxel and carboplatin, OR
        iii. Used as a single agent following multi-modality anthracycline based therapy

    OR
    b. Metastatic disease and one of the following:
        i. Used in combination with paclitaxel for first-line treatment of metastatic breast cancer, OR
        ii. Used as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease

AND

2. *For request for Herceptin, Herzuma, Ogivri or Ontruzant*: Inadequate response, intolerable side effect, or contraindication with Kanjinti or Trazimera

Covered Doses

Adjuvant Treatment

Administer according to one of the following doses and schedules for a total of 52 weeks of Herceptin therapy:

- During and following paclitaxel, docetaxel, or docetaxel/carboplatin:

        - Up to 4 mg/kg IV for the first dose, followed by up to 2 mg/kg IV weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel/carboplatin), followed by up to 6 mg/kg IV every three weeks.
    - As a single agent within three weeks following completion of multi-modality, anthracycline-based chemotherapy regimens:
        - Up to 8 mg/kg IV for the first dose, followed by up to 6 mg/kg IV every three weeks

Metastatic

Administer alone or in combination with paclitaxel, up to 4 mg/kg IV for the first dose, followed by up to 2 mg/kg IV once weekly until disease progression.

Coverage Period

Plan year

Gastric or gastroesophageal junction adenocarcinoma (HER2-positive)

1. Metastatic disease, **AND**
2. Either of the following:
    a. Used in combination with paclitaxel for first-line treatment of metastatic disease, OR
    b. Used as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease, **AND**
3. *For request for Herceptin, Herzuma, Ogivri or Ontruzant*: Inadequate response, intolerable side effect, or contraindication with Kanjinti or Trazimera

Covered Doses

Up to 8 mg/kg IV for the first dose, followed by up to 6 mg/kg IV every three weeks until disease progression

Coverage Period

Plan year

How Supplied

Herceptin®
- 150 mg single-dose vial (lyophilized powder for reconstitution)

Herzuma®
- 150 mg single-dose vial (lyophilized powder for reconstitution)
- 420 mg multiple-dose vial (lyophilized powder for reconstitution)

Trazimera™
- 420 mg multiple-dose vial (lyophilized powder for reconstitution)

Kanjinti™
- 150 mg single-dose vial (lyophilized powder for reconstitution)
- 420 mg multiple-dose vial (lyophilized powder for reconstitution)

Ogivri™
- 150 mg single-dose vial (lyophilized powder for reconstitution)
- 420 mg multiple-dose vial (lyophilized powder for reconstitution)

Ontruzant®
- 150 mg single-dose vial (lyophilized powder for reconstitution)

- 420 mg multiple-dose vial (lyophilized powder for reconstitution)

References

- For CMS Memorandum titled "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage", dated August 7, 2018 see: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf
- Herceptin (trastuzumab) [Prescribing information]. South San Francisco, CA: Genentech, Inc. 11/2018.
- Herzuma (trastuzumab-pkrb) [Prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc. 5/2019.
- Kanjinti (trastuzumab-anns) [Prescribing information]. Thousand Oaks, CA: Amgen. 10/2019.
- Ogivri (trastuzumab-dkst) [Prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc. 12/2020.
- Ontruzant (trastuzumab-dttb) [Prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc. 3/2020.
- Trazimera(trastuzumab-qyyp) [Prescribing information]. New York, NY: Pfizer Labs. 11/2020.

Policy Update

Date of initial review: 1Q2021
Date of next review: 4Q2021
Changes from previous policy version:

- New policy