Trastuzumab (Herceptin®)
Trastuzumab-anns (Kanjinti™)
Trastuzumab-dkst (Ogivri™)
Trastuzumab-dttb (Ontruzant®)
Trastuzumab-pkrb (Herzuma®)
Trastuzumab-qyyp (Trazimera™)

Place of Service Office Administration
Home Infusion Administration
Outpatient Facility Infusion Administration
Infusion Center Administration

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

Condition(s) listed in policy (*see criteria for details*)

- Breast cancer (HER2-positive)
- Colorectal cancer (HER2-positive)
- Esophageal cancer (HER2-positive)
- Esophagogastric junction cancer (HER2-positive)
- Gastric cancer (HER2-positive)
- Head and neck cancer, salivary gland tumors (HER2-positive)
- Hepatobiliary cancers - Cholangiocarcinoma or gallbladder cancer (HER2-positive)
- Uterine serous carcinoma (HER2-positive)

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Recombinant DNA-derived humanized anti-*HER2* monoclonal antibody which is a mediator of antibody-dependent cellular cytotoxicity (ADCC).

(1) Special instructions and pertinent information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for trastuzumab must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer (HER2-positive)

1. HER2-positivity, **AND**
2. If for Herceptin: Intolerable side effect with the preferred trastuzumab products, Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera, that is not expected with Herceptin, or contraindication to Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera.

Covered Doses

Neoadjuvant/Adjuvant:

Up to 4 mg/kg IV for the first dose, followed by 2 mg/kg IV weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose of Herceptin, can allow up to 6 mg/kg IV every three weeks to complete a total of 52 weeks of therapy.

OR

Up to 8 mg/kg IV for the first dose, followed by 6 mg/kg IV every three weeks for 52 weeks.

Recurrent or Metastatic:
Up to 4 mg/kg IV for the first dose, then up to 2 mg/kg IV every week
OR
Up to 8 mg/kg IV for the first dose, then up to 6 mg/kg IV every three weeks

For Leptomeningeal metastases: Up to 150 mg via intrathecal or intraventricular administration given once weekly

Coverage Period
Neoadjuvant/ Adjuvant therapy:
Cover maximum of 1 year (Number of doses is dependent on regimen)
No reauthorization.

Recurrent or Metastatic:
Yearly

ICD 10:
C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, Z85.3

Colorectal cancer (HER2-positive)
1. Disease is unresectable, advanced or metastatic, **AND**
2. Being used in combination with pertuzumab, lapatinib, or tucatinib, **AND**
3. HER2-positivity/amplified, **AND**
4. KRAS/NRAS wild-type (negative for mutation), **AND**
5. Patient has not received prior treatment with a HER2 inhibitor, **AND**
6. If for Herceptin: Intolerable side effect with the preferred trastuzumab products, Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera, that is not expected with Herceptin, or contraindication to Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera.

Covered Doses
Up to 8 mg/kg IV for the first dose, followed by up to 6 mg/kg IV every 3 weeks, OR
Up to 4 mg/kg IV for the first dose, followed by up to 2 mg/kg IV every week

Coverage Period
Yearly

ICD 10:
C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C19, C20, C21.8, C78.00-C78.02, C78.6, C78.7, Z85.038, Z85.068

Esophageal cancer, Esophagogastric junction cancer, or Gastric cancer (HER2-positive)
1. Disease is unresectable locally advanced, recurrent, or metastatic, **AND**
2. HER2-positivity, **AND**
3. Being used as first line therapy, **AND**
4. Given in combination with systemic chemotherapy, **AND**
5. If for Herceptin: Intolerable side effect with the preferred trastuzumab products, Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera, that is not expected with Herceptin, or contraindication to Kanjinti,

Herzuma, Ogivri, Ontruzant, and Trazimera.

Covered Doses
Up to 8 mg/kg for the first dose, followed by up to 6 mg/kg every 3 weeks
OR
Up to 6 mg/kg for the first dose, followed by up to 4 mg/kg every 2 weeks

Coverage Period
Yearly

ICD 10:
C15.3-C15.5, C15.8, C15.9, C16.0, D37.8, D37.9 C16.0-C16.6, C16.8, C16.9, D37.1, Z85.00, Z85.028

Head and neck cancer, salivary gland tumors (HER2-positive)

1. Diagnosis of salivary gland tumor, **AND**
2. Recurrent, unresectable, or metastatic disease, **AND**
3. HER2-positivity, **AND**
4. Being used as single agent or in combination with docetaxel or pertuzumab, **AND**
5. If for Herceptin: Intolerable side effect with the preferred trastuzumab products, Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera, that is not expected with Herceptin, or contraindication to Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera.

Covered Doses
Up to 8 mg/kg for the first dose, followed by up to 6 mg/kg every 3 weeks

Coverage Period
Indefinite

ICD-10:
C06.9, C07, C08.0, C08.1, C08.9

Hepatobiliary cancers (Cholangiocarcinoma and gallbladder cancer)

1. Being used for unresectable or metastatic disease, **AND**
2. HER2-positivity, **AND**
3. Given in combination with pertuzumab, **AND**
4. If for Herceptin: Intolerable side effect with the preferred trastuzumab products, Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera, that is not expected with Herceptin, or contraindication to Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera.

Covered Doses
Up to 8 mg/kg for the first dose, followed by up to 6 mg/kg every 3 weeks

Coverage Period
Indefinite

ICD-10:
C22.1, C23, C24.0, C24.8, C24.

Uterine serous carcinoma (HER2-positive)

1. Disease is advanced (stage III or IV) or recurrent, **AND**
2. HER2-positivity, **AND**
3. Given in combination with carboplatin and paclitaxel, **AND**
4. If for Herceptin: Intolerable side effect with the preferred trastuzumab products, Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera, that is not expected with Herceptin, or contraindication to Kanjinti, Herzuma, Ogivri, Ontruzant, and Trazimera.

Covered Doses
Up to 8 mg/kg IV for the first dose, then up to 6 mg/kg IV every three weeks

Coverage Period
Yearly

ICD 10:
C54.0-C54.3, C54.8, C54.9, C55

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for trastuzumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

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™

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

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Herceptin® (trastuzumab) [Prescribing information]. South San Francisco, CA: Genentech, Inc.; 2/2021.
- Herzuma (trastuzumab-pkrb) [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; 05/2019.
- Kanjinti (trastuzumab-anns) [Prescribing Information]. Thousand Oaks, CA: Amgen; 10/2022.
- Ogivri (trastuzumab-dkst). [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals; 2/2021.
- Ontruzant (trastuzumab-dttb). [Prescribing Information]. Jersey City, NJ: Organon; 6/2021.
- National Comprehensive Cancer Network. Biliary Tract Cancers (Version 2.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Breast Cancer (Version 4.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Central Nervous System Cancers (Version 1.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Colon Cancer (Version 2.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers (Version 2.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Gastric Cancer (Version 1.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Head and Neck Cancers (Version 2.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Rectal Cancer (Version 3.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Uterine Neoplasms (Version 2.2023). Available at http://www.nccn.org.
- Trazimera (trastuzumab-qyyp) [Prescribing Information]. New York, NY: Pfizer; 12/2020.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

- No clinical change to policy following routine annual review.