Reference number(s)
1905-A

Specialty Guideline Management Herceptin and Trastuzumab Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Herceptin	trastuzumab
Ogivri	trastuzumab-dkst
Kanjinti	trastuzumab-anns
Trazimera	trastuzumab-qyyp
Herzuma	trastuzumab-pkrb
Ontruzant	trastuzumab-dttb
Hercessi	trastuzumab-strf

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.

FDA-Approved Indications[1-7]

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

- as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- as part of a treatment regimen with docetaxel and carboplatin

- as a single agent following multi-modality anthracycline based therapy

Metastatic Breast Cancer

- In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

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

Compendial Uses[8-12]

- HER2-positive breast cancer
  - Neoadjuvant therapy
  - Treatment of recurrent, advanced, unresectable, or stage IV (M1) disease
  - Treatment for no response to preoperative systemic therapy
- Intra-cerebrospinal fluid (CSF) treatment for leptomeningeal metastases from HER2-positive breast cancer
- HER2-positive esophageal and esophagogastric junction cancer
- HER2-positive uterine serous carcinoma or carcinosarcoma
- HER2-amplified/positive and RAS and BRAF wild-type colorectal cancer
- HER2-positive salivary gland tumor
- HER2-positive biliary tract cancers
- HER2-amplified small bowel adenocarcinoma
- HER2-positive appendiceal neoplasms and cancers

All other indications are considered experimental/investigational and not medically necessary.

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).

Coverage Criteria

Breast Cancer[1-9]

Authorization of up to 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.

Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.

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.

Authorization of 12 months may be granted for intra-CSF treatment for leptomeningeal metastases from HER2-positive breast cancer.

Authorization of 12 months may be granted for treatment of HER2-negative metastatic breast cancer when used in combination with neratinib and fulvestrant or in combination with tucatinib with or without fulvestrant as third-line or later therapy.

Esophageal, Gastric, or Gastroesophageal Junction Cancer[1-8]

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.

Uterine Serous Carcinoma or Carcinosarcoma[8]

Authorization of 12 months may be granted for treatment of HER2-positive stage III-IV, recurrent, or metastatic uterine serous carcinoma or carcinosarcoma in combination with carboplatin and paclitaxel and continued as a single agent for maintenance therapy.

Colorectal Cancer[8,10-11]

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:

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

Salivary Gland Tumor[8,12]

Authorization of 12 months may be granted for treatment of recurrent unresectable or metastatic HER2-positive salivary gland tumors when used as a single agent or in combination with docetaxel or pertuzumab.

Biliary Tract Cancers[8]

Authorization 12 months may be granted for subsequent treatment of unresectable, resected gross residual (R2), or metastatic HER2-positive (IHC 3+/ISH +/NGS amplification) biliary tract cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer) when used in combination with pertuzumab or tucatinib.

Small Bowel Adenocarcinoma[8]

Authorization of 12 months may be granted for subsequent treatment of advanced or metastatic small bowel adenocarcinoma when all of the following criteria are met:

- The disease is HER2 amplified and RAS and BRAF wild-type (negative).
- The requested medication will be used in combination with pertuzumab or tucatinib.
- The member has not received previous treatment with a HER2 inhibitor.

Appendiceal Neoplasms and Cancers[8]

Authorization of 12 months may be granted for subsequent treatment of appendiceal neoplasms and cancers (including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified) when all of the following criteria are met:

- The disease is HER2 positive and RAS and BRAF wild-type (negative).
- The requested medication will be used in combination with pertuzumab or tucatinib.
- The member has not received previous treatment with a HER2 inhibitor.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section 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.

References

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. Ogivri [package insert]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
3. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2025.
4. Trazimera [package insert]. Cork, Ireland: Pfizer Ireland Pharmaceuticals; November 2020.
5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc.; December 2024.
6. Ontruzant [package insert]. Jersey City, NJ: Organon LLC; February 2025.
7. Hercessi [package insert]. Raleigh, NC: Accord BioPharma Inc.; September 2024.
8. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed February 13, 2026.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 3, 2025.
10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed September 5, 2025.
11. Tukysa [package insert]. Bothell, WA: Seagen, Inc.; January 2023.
12. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed September 3, 2025.