Clinical Policy: Trastuzumab/Biosimilars, Trastuzumab-Hyaluronidase

Reference Number: PA.CP.PHAR.228
Effective Date: 01/2018
Last Review Date: 04/2023

Revision Log

Description

- Trastuzumab (Herceptin®) is a human epidermal growth factor receptor 2 (HER2)/neu receptor antagonist.
- Trastuzumab-dkst (Ogivri™), trastuzumab-pkrb (Herzuma®), and trastuzumab-dttb (Ontruzant®), trastuzumab-qyyp (Trazimera™), and trastuzumab-anns (Kanjinti™) are Herceptin biosimilars.
- Trastuzumab-hyaluronidase-oysk (Herceptin Hylecta™) is a combination of trastuzumab and hyaluronidase, an endoglycosidase.

FDA Approved Indication(s)

Indications*	Description		Herceptin, Herzuma, Ogivri, Ontruzant, Trazimera, Kanjinti	Herceptin Hylecta
Adjuvant breast cancer	For adjuvant treatment of HER2-overexpressing node positive or node negative (ER/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	X	X
		As part of a treatment regimen with docetaxel and carboplatin	X	X
		As a single agent following multi-modality anthracycline based therapy	X	X
Metastatic breast cancer	In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer		X	X
	As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease		X	X
Gastric cancer	In combination with cisplatin and capecitabine or 5-fluorouracil for the treatment of patients with HER2-		X	–

Indications*	Description	Herceptin, Herzuma, Ogivri, Ontruzant, Trazimera, Kanjinti	Herceptin Hylecta
	overexpressing metastatic gastric or gastroesophageal junction (esophagogastric junction; EGJ) adenocarcinoma who have not received prior treatment for metastatic disease		

*Select patients for therapy based on an FDA-approved companion diagnostic for trastuzumab.
** High-risk is defined as ER/PR positive with one of the following features: tumor size > 2 cm, age < 35 years, or tumor grade 2 or 3>

Policy/Criteria
It is the policy of PA Health & Wellness® that Herceptin/biosimilars and Herceptin Hylecta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of HER2-positive breast cancer or leptomeningeal metastases from HER2-positive breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. If request is for Herceptin, Herzuma, or Ontruzant, member meets one of the following (a, b, or c):
   a. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      i. Kanjinti, Ogivri, Trazimera;
      ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;
      **Prior authorization may be required*
   b. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;
      **Prior authorization may be required*
   c. Request is for Stage IV or metastatic cancer;
5. Request meets one of the following (a, b, c, or d):
   a. Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti: dose does not exceed 8 mg/kg IV for adjuvant therapy or 4 mg/kg IV for treatment of metastatic disease (*see Appendix D for dose rounding guidelines*);
   b. Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti: intrathecal administration for leptomeningeal metastasis;
   c. Herceptin Hylecta: dose does not exceed 600 mg/10,000 units SC every 3 weeks (*see Appendix D for dose rounding guidelines*);

d. Dose/product is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Gastric, Esophageal and Esophagogastric Junction Cancer (must meet all):

1. Diagnosis of HER2-positive gastric, esophageal, or EGJ adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with one of the following* (a, b, c, d, e, or f):
   a. A platinum agent (i.e., either cisplatin or oxaliplatin) and either capecitabine or 5-fluorouracil;*
   b. Fluorouracil and irinotecan;
   c. Paclitaxel with or without carboplatin or cisplatin;
   d. Docetaxel with or without cisplatin;
   e. Capecitabine or 5-fluorouracil;
   f. Docetaxel, cisplatin or oxaliplatin, and fluorouracil

   **Prior authorization may be required.*
5. If request is for Herceptin, Herzuma, or Ontruzant, member meets one of the following (a, b, or c):
   a. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      i. Kanjinti, Ogivri, Trazimera;
      ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;

      **Prior authorization may be required*
   b. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;
      **Prior authorization may be required*
   c. Request is for Stage IV or metastatic cancer;
6. Request meets one of the following (a or b):
   a. Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti: dose does not exceed 8 mg/kg IV (*see Appendix D for dose rounding guidelines*);
   b. Dose/product is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Endometrial Carcinoma (off-label) (must meet all):

1. Diagnosis of HER2-positive endometrial carcinoma with serous histology;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is advanced (i.e., stage III/IV) or recurrent;
5. Prescribed in combination with carboplatin and paclitaxel;*
   **Prior authorization may be required.*

6. If request is for Herceptin, Herzuma, or Ontruzant, member meets one of the following (a, b, or c):
    a. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
        iii. Kanjinti, Ogivri, Trazimera;
        iv. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;
        **Prior authorization may be required*
    b. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;
        **Prior authorization may be required*
    c. Request is for Stage IV or metastatic cancer;
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Colorectal Cancer (off-label) (must meet all):
1. Diagnosis of advanced or metastatic colorectal cancer and all of the following (a, b, and c):
    a. Disease is HER2 positive;
    b. Disease is wild-type *RAS* (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use);
    c. Wild-type *BRAF*;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. If request is for Herceptin, Herzuma, or Ontruzant, member meets one of the following (a, b, or c):
    a. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
        i. Kanjinti, Ogivri, Trazimera;
        ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;
        **Prior authorization may be required*
    b. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;
        **Prior authorization may be required*
    c. Request is for Stage IV or metastatic cancer;
5. No previous use of a HER2 inhibitor therapy (e.g., trastuzumab, Kadcyla®, Tykerb®, Perjeta®);
6. Prescribed in combination with Perjeta (pertuzumab), Tukysa (tucatinib) or Tykerb (lapatinib);*
    **Prior authorization may be required.*

7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

E. Salivary Gland Tumor (off-label) (must meet all)**:**

1. Diagnosis of HER2-positive salivary gland tumor;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is recurrent;
5. Prescribed in one of the following manners (a, b, or c):
   a. Single agent;
   b. Combination with docetaxel;*
   c. Combination with Perjeta;*

   **Prior authorization may be required.*
6. If request is for Herceptin, Herzuma, or Ontruzant, member meets one of the following (a, b, or c):
   a. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      i. Kanjinti, Ogivri, Trazimera;
      ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;

      **Prior authorization may be required*
   b. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;

      **Prior authorization may be required*
   c. Request is for Stage IV or metastatic cancer*;*

Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**Approval duration: 6 months**

F. Gallbladder Cancer or Cholangiocarcinoma (off-label) (must meet all):

1. Diagnosis of HER2-positive gallbladder cancer or cholangiocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is unresectable, resected gross residual (R2) disease or metastatic;
5. Prescribed in combination with Perjeta*;

   **Prior authorization may be required.*
6. If request is for Herceptin, Herzuma, or Ontruzant, member meets one of the following (a, b, or c):
   a. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      i. Kanjinti, Ogivri, Trazimera;

ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;
**Prior authorization may be required*

b. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;
**Prior authorization may be required*

c. Request is for Stage IV or metastatic cancer*;*

7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
Approval duration: 6 months

G. Other diagnoses/indications (must meet all):

1. Member meets one of the following (a, b, or c):
   a. Request is for Stage IV or metastatic cancer;
   b. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      i. Kanjinti, Ogivri, Trazimera;
      ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;
      **Prior authorization may be required*
   c. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;
      **Prior authorization may be required*
2. Refer to the off -label use policy PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for Herceptin, Herzuma, or Ontruzant, member meets one of the following (a, b, or c):
   a. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      i. Kanjinti, Ogivri, Trazimera;
      ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;
      **Prior authorization may be required*
   b. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;

**Prior authorization may be required*

c. Request is for Stage IV or metastatic cancer;

4. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. Breast cancer (i, ii, or iii):
      i. Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti: new dose does not exceed 8 mg/kg IV for adjuvant therapy or 4 mg/kg IV for treatment of metastatic disease (*see Appendix D for dose rounding guidelines*);
      ii. Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti: intrathecal administration for leptomeningeal metastases;
      iii. Herceptin Hylecta: new dose does not exceed 600 mg/10,000 units SC every 3 weeks (*see Appendix D for dose rounding guidelines*);
   b. Gastric, esophageal, EGJ cancer: Herceptin, Herzuma, Ogivri, Ontruzant, Trazimera, Kanjinti : new dose does not exceed 8 mg/kg IV(*see Appendix D for dose rounding guidelines*);
   c. New dose/product is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member meets one of the following (a, b, or c):
   a. Request is for Stage IV or metastatic cancer;
   b. If request if for Herceptin, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      iii. Kanjinti, Ogivri, Trazimera;
      iv. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant and Herzuma;
      **Prior authorization may be required*
   c. If request is for Herzuma or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera;
      **Prior authorization may be required*

Approval duration: Duration of request or 6 months (whichever is less); or

3. Refer to the off -label use policy PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
EGJ: esophagogastric junction
HER2: human epidermal growth factor receptor 2
KRAS: Kirsten rat sarcoma 2 viral oncogene homologue
NRAS: neuroblastoma RAS viral oncogene homologue

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):
  - Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti: cardiomyopathy, infusion reactions, embryo-fetal toxicity, pulmonary toxicity
  - Herceptin Hylecta: cardiomyopathy, embryo-fetal toxicity, pulmonary toxicity

Appendix D: Dose Rounding Guidelines

Weight-based Dose Range	Vial Quantity Recommendation
≤ 157.49 mg	1 vial of 150 mg
157.5 mg to 314.99 mg	2 vials of 150 mg
315 mg to 440.99 mg	1 vial of 420 mg
441 mg to 598.49 mg	1 vial of 150 mg and 1 vial 420 mg
598.5 mg to 881.99 mg	2 vials of 420 mg
882 mg to 1,039.49 mg	1 vial of 150 mg and 2 vials of 420 mg
1,039.5 mg to 1,322.99 mg	3 vials of 420 mg

IV. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri), Trastuzumab-dttb (Ontruzant), Trastuzumab-pkrb (Herzuma), Trastuzumab-qyyp (Trazimera), Trastuzumab-hyaluronidase-oysk (Herceptin Hylecta), Trastuzumab-anns (Kanjinti)	Adjuvant treatment, breast cancer	Administer according to one of the following doses and schedules for a total of 52 weeks: ***Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti:*** During and following paclitaxel, docetaxel, or docetaxel/carboplatin: • Initial dose of 4 mg/kg as an IV infusion over 90 minutes then at 2 mg/kg as an IV infusion over 30 minutes weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel/carboplatin). • One week following the last weekly dose of the trastuzumab product, administer trastuzumab product at 6 mg/kg as an IV infusion over 30 to 90 minutes every 3 weeks. ***Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti:*** As a single agent within 3 weeks following completion of multi-modality, anthracycline based chemotherapy regimens:	8 mg/kg

Drug Name	Indication	Dosing Regimen	Maximum Dose
		• Initial dose: 8 mg/kg as an IV infusion over 90 minutes. • Subsequent doses: 6 mg/kg as an IV infusion over 30 to 90 minutes every 3 weeks	
		Herceptin Hylecta (subcutaneous product): 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: 600 mg trastuzumab and 10,000 units hyaluronidase administered subcutaneously over approximately 2-5 minutes once every 3 weeks	600 mg/10,000 units every 3 weeks
Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri), Trastuzumab-dttb (Ontruzant), Trastuzumab-pkrb (Herzuma), Trastuzumab-qyyp (Trazimera), Trastuzumab-hyaluronidase-oysk (Herceptin Hylecta), Trastuzumab-anns (Kanjinti)	Metastatic treatment, breast cancer	***Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti:*** As a single agent, or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute intravenous infusions until disease progression.	4 mg/kg
		Herceptin Hylecta (subcutaneous product): As a single agent or in combination with paclitaxel: 600 mg trastuzumab and 10,000 units hyaluronidase administered subcutaneously over approximately 2-5 minutes once every 3 weeks.	600 mg/10,000 units every 3 weeks
Trastuzumab (Herceptin),	Metastatic gastric cancer	***Herceptin, Herzuma, Ogivri, Ontruzant, Trazimera, Kanjinti:***	8 mg/kg

Drug Name	Indication	Dosing Regimen	Maximum Dose
Trastuzumab-dkst (Ogivri), Trastuzumab-dttb (Ontruzant), Trastuzumab-qyyp (Trazimera), Trastuzumab-anns (Kanjinti)		Administer at an initial dose of 8 mg/kg as a 90 minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks until disease progression.	

V. Product Availability

Drug Name	Availability*
Trastuzumab (Herceptin)	Single-dose vial: 150 mg
Trastuzumab-dkst (Ogivri)	Single-dose vial: 150 mg Multi-dose vial: 420 mg
Trastuzumab-pkrb (Herzuma)	Single-dose vial: 150 mg Multi-dose vial: 420 mg
Trastuzumab-dttb (Ontruzant)	Single-dose vial: 150 mg Multi-dose vial: 420 mg
Trastuzumab-qyyp (Trazimera)	Single-dose vial: 150 mg Multi-dose vial: 420 mg
Trastuzumab-hyaluronidase-oysk (Herceptin Hylecta)	Single-dose vial: 600 mg (trastuzumab)/10,000 units (hyaluronidase)/5 mL
Trastuzumab-anns (Kanjinti)	Single-dose vial: 150 mg Multi-dose vial: 420 mg

**All products are supplied as a powder for reconstitution with the exception of Herceptin Hylecta which is supplied as a solution.*

VI. References

1. Herceptin Prescribing Information. South San Francisco, CA: Genentech, Inc.; February 2021. Available at https://www.gene.com/download/pdf/herceptin_prescribing.pdf. Accessed January 20, 2023.
2. Ogivri Prescribing Information. Morgantown, WV: Mylan GmbH.; February 2021. Available at https://www.ogivrihcp.com/en/about/about-ogivri?gclid=EAIaIQobChMIrZTvxp3X_AIVXRXUAR3weggDEAAYASAAEgJfI_D_BwE&gclsrc=aw.ds. Accessed January 20, 2023.
3. Herzuma Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2019. https://www.herzuma.com/ . Accessed January 20, 2023.
4. Ontruzant Prescribing Information. Jersey City, NJ: Organon; June 2021. https://www.organon.com/product/usa/pi_circulars/o/ontruzant/Ontruzant-pi.pdf. Accessed January 20, 2023.

5. Trazimera Prescribing Information. New York, NY: Pfizer Labs; November 2020. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=12725. Accessed January 20, 2023.
6. Herceptin Hylecta Prescribing Information. South San Francisco, CA: Genentech, Inc.; February 2019. Available at https://www.gene.com/download/pdf/herceptin_hylecta_prescribing.pdf. Accessed January 20, 2023.
7. Kanjinti Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; October 2019. Available at https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/kanjinti/kanjinti_pi.ashx. Accessed January 20, 2023.
8. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 7, 2023.
9. Fahrenbruch R, Kintzel P, Bott AM., et al. Dose rounding of biologic and cytotoxic anticancer agents: a position statement of the hematology/oncology pharmacy association. Journal of Oncology Practice. 2018;14(3)e130-e136.
10. National Comprehensive Cancer Network. Breast Cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 7, 2023.
11. National Comprehensive Cancer Network. Gastric Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed January 10, 2023.
12. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Version 5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed January 10, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
Q5114	Injection, trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg
Q5117	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg

Reviews, Revisions, and Approvals	Date	Approval Date
1Q2018 annual review. Ogivri added.	01/2018	

Reviews, Revisions, and Approvals	Date	Approval Date
Age, specialist and dosing added. Breast cancer criteria sets combined; criteria limited to a diagnosis of HER2+ breast cancer. CNS breast cancer metastatic disease off-label criteria limited to diagnosis. Off-label uses removed from gastric cancer criteria - FDA indications cover through NCCN category 2A. HER2-positive lung cancer removed as an off-label indication per NCCN. References reviewed and updated.		
2Q 2019 annual review: Herceptin biosimilars and Herceptin combination product added (biosimilars - Herzuma, Ontruzant; combination product - Herceptin Hylecta); intrathecal treatment for breast cancer related CNS metastasis is moved to the breast cancer criteria set; NCCN recommended use for endometrial carcinoma are added; references reviewed and updated.	04/2019	
2Q 2020 annual review: added new Ogivri formulation: 150 mg single-dose vial; added Herceptin biosimilar, Kanjinti; Herceptin product availability for multi-dose vial corrected from 420 mg to 440 mg; references updated; newly FDA-approved indication for gastric cancer and new 150 mg vial formulation for Herzuma added; references updated.added NCCN compendium-supported indications of colon and rectal cancer; incorporated NCCN compendium-supported indication of leptomeningeal metastases from HER2-positive breast cancer into breast cancer criteria; added appendix D: dose rounding guidelines; added reference to appendix D within criteria; references reviewed and updated.	04/2020	
2Q 2021 annual review: revised requirement of medical justification for inability to use preferred Kanjinti, Ogivri, or Trazimera to “must use” language; added choice of oxaliplatin, in addition to cisplatin, for combination treatment of gastric cancers per NCCN; updated product availability for Herceptin and Kanjinti; references reviewed and updated.	04/2021	
Per NCCN support, added wild-type *BRAF* criterion for colorectal cancer and choice of oxaliplatin, in addition to cisplatin, for combination treatment of gastric cancers; updated product availability for Herceptin, Kanjinti, and Trazimera; Per August SDC and prior clinical guidance, modified biosimilar redirection requirements for Herceptin to require use of Ogivri, Trazimera, Kanjinti, Ontruzant and Herzuma in a step-wise manner; for Ontruzant and Herzuma modified redirection to require use of Ogivri, Trazimera, and Kanjinti; for salivary gland tumor indication added redirection to preferred biosimilars per NCCN Compendium; references reviewed and updated.	10/2021	
2Q 2022 annual review: added qualifiers of “advanced” and “recurrent” for gastric, esophageal, or EGJ adenocarcinoma; clarified other diagnoses section to clarify intent for biosimilar steerage; references reviewed and updated.	04/2022	
2Q 2023 annual review: added gallbladder cancer and cholangiocarcinoma as NCCN supported off-label indication; references reviewed and updated.	04/2023	