Clinical Policy: Trastuzumab/Biosimilars, Trastuzumab-Hyaluronidase

Reference Number: PA.CP.PHAR.228
Effective Date: 01/2018
Last Review Date: 04/2025

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®), trastuzumab-anns (Kanjinti®) and trastuzumab-strf (Hercessi™) are Herceptin biosimilars.
- Trastuzumab-hyaluronidase-oysk (Herceptin Hylecta™) is a combination of trastuzumab and hyaluronidase, an endoglycosidase.

FDA Approved Indication(s)

Indications*	Description		Herceptin, Hercessi, 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-overexpressing metastatic gastric or		X	–

Indications*	Description	Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant, Trazimera, Kanjinti	Herceptin Hylecta
	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, limited brain metastases, or extensive brain 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, Hercessi, 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, Hercessi and Herzuma;
      **Prior authorization may be required*
   b. If request is for Herzuma, Hercessi or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera or member has failed Kanjinti, Ogivri, and 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, Hercessi, 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, Hercessi, 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. Disease is advanced, recurrent, unresectable, metastatic or not a surgical candidate;
5. Prescribed in combination with systemic chemotherapy;
   **Prior authorization may be required.*
6. If request is for Herceptin, Hercessi, 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, Hercessi and Herzuma;
      **Prior authorization may be required*
   b. If request is for Herzuma, Hercessi or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera or member has failed Kanjinti, Ogivri, and Trazimera;
      **Prior authorization may be required*
   c. Request is for Stage IV or metastatic cancer;
7. Request meets one of the following (a or b):
   a. Herceptin, Hercessi, 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 or carcinosarcoma;
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 one of the following ways (a or b):
   a. In combination with carboplatin and paclitaxel;*
   **Prior authorization may be required.*
   b. As a single agent for maintenance therapy;
6. If request is for Herceptin, Hercessi, 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, Hercessi and Herzuma;

**Prior authorization may be required*

b. If request is for Herzuma, Hercessi or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera or member has failed Kanjinti, Ogivri, and 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. Member meets one of the following (a or b):
   a. Diagnosis of unresectable or medically inoperable, advanced, or metastatic colorectal cancer and disease is all of the following (i, ii, and iii):
      i. HER2 positive;
      ii. Wild-type *RAS* (defined as wild-type in both KRAS and NRAS [i.e., KRAS and NRAS mutation-negative] as determined by an FDA-approved test for this use);
      iii. Wild-type *BRAF (i.e.,* BRAF mutation-negative);
   b. Ineligible for or progressed on checkpoint inhibitor immunotherapy;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. If request is for Herceptin, Hercessi, 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, Hercessi and Herzuma;

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

      **Prior authorization may be required*
   c. Request is for Stage IV or metastatic cancer;
5. Prescribed in combination with Perjeta (pertuzumab), Tukysa (tucatinib) or Tykerb (lapatinib);*

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

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*or Tukysa*;
   **Prior authorization may be required.*
6. If request is for Herceptin, Hercessi, 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, Hercessi and Herzuma;

**Prior authorization may be required*

b. If request is for Herzuma, Hercessi or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera or member has failed Kanjinti, Ogivri, and 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, Hercessi and Herzuma;
      **Prior authorization may be required*
   c. If request is for Herzuma, Hercessi or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Kanjinti, Ogivri, Trazimera or member has failed Kanjinti, Ogivri, and 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.PHARM.01) applies;
2. Documentation of positive response to therapy;
3. For adjuvant breast cancer therapy, member has received ≤ 52 weeks of therapy total;
4. If request is for Herceptin, Hercessi, 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, Hercessi and Herzuma;
      **Prior authorization may be required*
   b. If request is for Herzuma, Hercessi or Ontruzant, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are

contraindicated: Kanjinti, Ogivri, Trazimera or member has failed Kanjinti, Ogivri, and Trazimera;
**Prior authorization may be required*

c. Request is for Stage IV or metastatic cancer;

5. 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, Hercessi, 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, Hercessi, 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, Hercessi, 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 *(total of 52 weeks for adjuvant breast cancer therapy)*

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.PHARM.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):
      i. Kanjinti, Ogivri, Trazimera;
      ii. If member has failed Kanjinti, Ogivri, and Trazimera, then member must use Ontruzant, Hercessi and Herzuma;
      **Prior authorization may be required*
   c. If request is for Herzuma, Hercessi 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

BRAF: v-Raf murine sarcoma viral oncogene homolog B1
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): cardiomyopathy, embryo-fetal toxicity, pulmonary toxicity
  - Additionally, Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti, Hercessi for infusion reactions

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

Appendix E: General Information

Residual Tumor (R) Classification		
R0	no residual tumor	resected, negative margin
R1	microscopic residual tumor	resected, positive margin
R2	macroscopic residual tumor	resected, gross residual disease

IV. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri), Trastuzumab-dttb (Ontruzant), Trastuzumab-pkrb (Herzuma),	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, Hercessi:*** 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).	8 mg/kg

Drug Name	Indication	Dosing Regimen	Maximum Dose
Trastuzumab-qyyp (Trazimera), Trastuzumab-hyaluronidase-oysk (Herceptin Hylecta), Trastuzumab-anns (Kanjinti), Trastuzumab-strf (Hercessi)		• 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, Hercessi:*** As a single agent within 3 weeks following completion of multi-modality, anthracycline based chemotherapy regimens: • 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	Metastatic treatment, breast cancer	***Herceptin, Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti, Hercessi:*** 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

Drug Name	Indication	Dosing Regimen	Maximum Dose
(Herceptin Hylecta), Trastuzumab-anns (Kanjinti), Trastuzumab-strf (Hercessi)			
Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri), Trastuzumab-dttb (Ontruzant), Trastuzumab-qyyp (Trazimera), Trastuzumab-anns (Kanjinti), Trastuzumab-strf (Hercessi)	Metastatic gastric cancer	***Herceptin, Herzuma, Ogivri, Ontruzant, Trazimera, Kanjinti, Hercessi:*** 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.	8 mg/kg

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
Trastuzumab-strf (Hercessi)	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.*
*** Product available with or without diluent provided*

VI. References

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7. Kanjinti Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; December 2024. Available at https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Kanjinti/kanjinti_pi.pdf. Accessed January 13, 2025.
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12. Hermanek P and Wittekind C. Residual tumor (R) classification and prognosis. Semin Surg Oncol. 1994 Jan-Feb;10(1):12-20.

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

HCPCS Codes	Description
Q5117	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg
Q5146	Injection, trastuzumab-strf, biosimilar, (Hercessi), 10 mg

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

Reviews, Revisions, and Approvals	Date
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
2Q 2024 annual review: for adjuvant breast cancer continued therapy, added member has received ≤ 52 weeks of therapy per PI; for gastric, esophageal, or EGJ, added option for unresectable disease, revised prescribed combination therapy to "systemic chemotherapy" as additional regimens options available per NCCN; for endometrial carcinoma added option to be prescribed as single agent for maintenance therapy per NCCN; for colorectal cancer, removed requirement for no previous use of HER2 inhibitor therapy and added tucatinib as option to be prescribed in combination with; for gallbladder cancer or cholangiocarcinoma, added option for treatment with resected gross residual (R2) disease per NCCN; residual (R) tumor classification added to Appendix F; for Ogivri, updated product availability of 420 mg multi-dose vial supplied with or without diluent; references reviewed and updated.	04/2024
RT4: added Hercessi to policy as non-preferred biosimilar. HCPCS code added [Q5146] and removed codes [J3590, C9399]	12/2024
2Q 2025 annual review: no significant changes; references reviewed and updated.	04/2025