JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP051
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Herceptin, Ogivri, Kanjinti, Trazimera, Herzuma, Ontruzant**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Herceptin, Herzuma , Kanjinti, Ogivri, Ontruzant, Trazimera

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I. POLICY

A. Herceptin (trastuzumab), Ogivri (trastuzumab-dkst), Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Ogivri, Kanjinti, Trazimera, Herzuma, or Ontruzant may be approved for patients who meet the following:
   1. Breast Cancer
      a. Documentation has been submitted showing the requested trastuzumab product will be used in one of the following clinical situations:
         I. Neoadjuvant treatment of HER2-positive confirmed breast cancer as part of a complete treatment regimen
         II. Adjuvant treatment of HER2-positive confirmed breast cancer
         III. Treatment of HER2-positive confirmed recurrent or metastatic breast cancer
         IV. Intra-CSF treatment for leptomeningeal metastases from breast cancer
   2. Esophageal, Gastric, or Gastroesophageal Junction Cancer
      a. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of HER2-positive- confirmed esophageal, gastric, or gastroesophageal junction cancer
         II. The requested trastuzumab product will be used in combination with chemotherapy
   3. Uterine Serous Carcinoma
      a. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of HER2-positive- confirmed advanced or recurrent uterine serous carcinoma
         II. The requested trastuzumab product will be used in combination with carboplatin and paclitaxel
   4. Colorectal Cancer
      a. Documentation has been submitted showing the following:
         I. The requested trastuzumab product will be used in combination with with pertuzumab or lapatinib for treatment of colorectal cancer with confirmed HER2-amplified and RAS and BRAF wild-type disease
            • Additionally, documentation showing one of the following:

- Patient is not appropriate for intensive therapy
- The requested trastuzumab product will be used as subsequent therapy for progression of advanced or metastatic disease

5. Salivary Gland Tumor
   a. Documentation has been submitted showing the requested trastuzumab product will be used for treatment of recurrent HER2-positive-confirmed salivary gland tumors with distant metastases

B. Herceptin may be approved for the following
   1. Patient meets the initial coverage criteria listed above for the biosimilar products
   2. Documentation has been submitted showing the patient has hypersensitivity to the biosimilar products, or provider has a clinical justification as to why the patient cannot use the biosimilar products

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment
   1. Limitation: Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

IV. EXCLUSIONS

A. Herceptin, Ogivri, Kanjinti, Trazimera, Herzuma, and Ontruzant will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, trastuzumab, excludes biosimilar, 10 mg	J9355
Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg	Q5112
Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg	Q5113
Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	Q5114
Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	Q5116
Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	Q5117

VII. REFERENCES

1. Herceptin [prescribing information]. South San Francisco, CA: Genentech, Inc.; November 2018.
2. Kanjinti [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; October 2019.
3. Ogivri [prescribing information]. Zurich, Switzerland: Mylan GmbH; November 2019.
4. Trazimera [prescribing information]. Cork, Ireland: Pfizer; November 2019.
5. Herzuma [prescribing information]. Incheon, Republic of Korea: Celltrion, Inc. May 2019.
6. Ontruzant [prescribing information]. Whitehouse Station, NJ: Merck. March 2020.
7. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 10, 2022.
8. Thorpe LM, Schrock AB, Erlich RL, et al. Significant and durable clinical benefit from trastuzumab in 2 patients with HER2-amplified salivary gland cancer and a review of the literature. Head Neck. 2017;39(3): E40-E44.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

Review Dates: 04/20/2022

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