This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
3985-D

POLICY Document for HERCEPTIN

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
TRASTUZUMAB

PREFERRED PRODUCTS: HERCEPTIN, HERCEPTIN HYLECTA, KANJINTI, and TRAZIMERA

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the trastuzumab products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Trastuzumab Products

	Product(s)
Preferred	• **Herceptin** (trastuzumab) • **Herceptin Hylecta** (trastuzumab and hyaluronidase-oysk) • **Kanjinti** (trastuzumab-anns) • **Trazimera** (trastuzumab-qyyp)
Targeted	• **Herzuma** (trastuzumab-pkrb) • **Ogivri** (trastuzumab-dkst)

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

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II. EXCEPTION CRITERIA

Coverage for the targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.

B. Member has had a documented intolerable adverse event to at least three of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication).

Section 2: Clinical Criteria

STANDARD MEDICARE PART B MANAGEMENT

HERCEPTIN (trastuzumab)

KANJINTI (trastuzumab-anns)

OGIVRI (trastuzumab-dkst)

TRAZIMERA (trastuzumab-qyyp)

HERZUMA (trastuzumab-pkrb)

ONTRUZANT (trastuzumab-dttb)

POLICY

I. 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.

A. FDA-Approved Indications

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

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1. Adjuvant breast cancer
   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

   a. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   b. As part of a treatment regimen with docetaxel and carboplatin
   c. As a single agent following multi-modality anthracycline based therapy
2. Metastatic breast cancer
   a. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
   b. As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease
3. 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

B. Compendial Uses
   1. HER2-positive breast cancer:
      a. Neoadjuvant therapy
      b. Treatment of recurrent or stage IV (M1) disease
   2. Intra-cerebrospinal fluid (CSF) treatment of leptomeningeal metastases from breast cancer
   3. HER2-positive esophageal and esophagogastric junction cancer
   4. HER2- positive advanced and recurrent uterine serous carcinoma
   5. HER2-positive recurrent salivary gland tumors with distant metastases
   6. HER2-amplified and RAS wild-type colorectal cancer in combination with pertuzumab or lapatinib
   7. HER2-positive non-small cell lung cancer
   8. Prostate cancer
   9. Malignant meningitis

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

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1. Authorization of 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.
2. Authorization of 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.
3. Authorization of 12 months may be granted for treatment of HER2-positive recurrent or metastatic breast cancer.
4. Authorization of 12 months may be granted for intra-CSF treatment of leptomeningeal metastases from breast cancer.

B. Esophageal, gastric, or esophagogastric junction cancer
Authorization of 12 months may be granted for treatment of HER2-positive esophageal, gastric, or esophagogastric junction cancer.

C. Uterine serous carcinoma
Authorization of 12 months may be granted for treatment of HER2-positive advanced and recurrent uterine serous carcinoma.

D. Salivary gland tumors
Authorization of 12 months may be granted for treatment of HER2-positive recurrent salivary gland tumors with distant metastases.

E. Colorectal Cancer
Authorization of 12 months may be granted for treatment of HER2-amplified colorectal cancer.

F. Non-small cell lung cancer
Authorization of 12 months may be granted for treatment of HER2-positive non-small cell lung cancer.

G. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

H. Malignant meningitis
Authorization of 12 months may be granted for treatment of malignant meningitis

III. CONTINUATION OF THERAPY

Authorization may be granted for all members (including new members) who are continuing with Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant therapy when all of the criteria below are met. Authorization

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

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duration will be 6 months for neoadjuvant treatment of breast cancer and 12 months for other settings or conditions.

A. The member is currently receiving treatment with Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant.
B. Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant is being used to treat a diagnosis or condition enumerated in Section II.
C. Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma, or Ontruzant has been effective for treating the diagnosis or condition.

UNIVERSAL CRITERIA

POLICY for Herceptin Hylecta

The Specialty Universal Med B Criteria ensure appropriate utilization of Specialty medications and confirm that selection elements established in the FDA-approved product labeling and relevant compendia are followed. The criteria may be applied in situations where specific criteria are pending development.

Authorization of 12 months may be granted for a requested medication when clinically appropriate

REFERENCES:

SECTION 1

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2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
3. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc; October 2019.
4. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2019.
5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc; May 2019.
6. Ogivri [package insert]. Steinhausen, Switzerland: Mylan GmbH; November 2019.

SECTION 2

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; November 2018.
2. Kanjinti [package insert]. Thousand Oaks, CA: Amgen, Inc.; October 2019.
3. Ogivri [package insert]. Zurich, Switzerland: Mylan GmbH; November 2019.
4. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2019.
5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc. May 2019.
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This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

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