### Prescription Drugs

**Effective Date:** January 1, 2020  
**Original Policy Date:** March 16, 2011  
**Last Review Date:** December 6, 2019  

### Antineoplastic Agents

**Subject:** Trastuzumab  
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### Description

**Trastuzumab**

*Herceptin (trastuzumab), Herzuma (trastuzumab-pkrb)*, **Kanjinti** (trastuzumab-anns), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb)*, **Trazimera (trastuzumab-qyyyp)*

Bolded medications are the preferred products

*These medications are included in this policy but are not available in the market as of yet.

### Background

Herceptin and its biosimilars are monoclonal antibodies that selectively binds with high affinity to the Human Epidermal Growth Factor Receptor – 2 (HER2) protein. Herceptin and its biosimilars are mediators of antibody-dependent cellular cytotoxicity (ADCC). Herceptin and its biosimilars effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not over-express HER2. Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera are biosimilars which means that the biological products are approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product (1-6).

### Regulatory Status

FDA-approved indication: Herceptin and its biosimilars are indicated for the adjuvant treatment of HER 2 overexpressing breast cancer and the treatment of HER 2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (1-6).
Herceptin and its biosimilars carry a boxed warning regarding possible risks for cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Trastuzumab use can result in cardiac failure that manifests as congestive heart failure (CHF) or decreased left ventricular ejection fraction (LVEF), with greatest risk when administered concurrently with anthracyclines (1).

Exposure to Herceptin or its biosimilars during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies
Afinitor, Halaven, Herceptin Hyllecta, Ibrance, Kadcyla, Perjeta, Tykerb

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Herceptin and its biosimilars may be considered medically necessary for patients 18 years of age or older for the treatment of HER-2 overexpressing breast cancer or HER-2 overexpressing metastatic or gastroesophageal junction adenocarcinoma and if the conditions indicated below are met.

Herceptin and its biosimilars may be considered investigational in patients under age 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. HER-2 overexpressing breast cancer
2. HER-2 overexpressing metastatic gastric or gastroesophageal junction (GEJ) Adenocarcinoma
3. Herceptin only: Patient MUST have tried the preferred product (Kanjinti) unless
the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

**Prior – Approval Renewal Requirements**

Same as above

**Policy Guidelines**

**Pre – PA Allowance**

None

**Prior - Approval Limits**

**Duration** 12 months

**Prior – Approval Renewal Limits**

Same as above

**Rationale**

**Summary**

Herceptin and its biosimilars are monoclonal antibodies that selectively bind with high affinity to the HER2 protein. Herceptin and its biosimilars are mediators of antibody-dependent cellular cytotoxicity (ADCC). Herceptin and its biosimilars effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not overexpress HER2 (1-6).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Herceptin and its biosimilars while maintaining optimal therapeutic outcomes.

**References**

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.