

**Subject:** Trastuzumab Agents

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## Overview

This document addresses the use of Herceptin Hylecta (trastuzumab; hyaluronidase) and Herceptin (trastuzumab) biosimilar products which include Ogivri, Herzuma, Ontruzant, Trazimera, and Kanjinti. Herceptin is a monoclonal antibody for HER2/neu receptors for use in HER2-overexpressing adjuvant and metastatic breast cancer and metastatic gastric or gastroesophageal junction adenocarcinoma. The following table list the agents included in the class according to their FDA approval dates:

Name	Biosimilar name	Dosage vial	FDA Approval Date	FDA Indications		
				Treatment of HER2-overexpressing metastatic breast cancer	Adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer	HER2+ metastatic gastric or gastroesophageal junction adenocarcinoma
<b>Herceptin</b> (Genentech)	trastuzumab	150 mg vial 420 mg/vial (IV only)	9/25/1998	X	X	X
<b>Ogivri</b> (Mylan/GMBH)	trastuzumab-dkst	420 mg/vial (IV only)	12/01/2017	X	X	X
<b>Herzuma</b> (Teva/Celltrion)	trastuzumab-pkrb	420 mg vial (IV only)	12/14/2018	X	X	X
<b>Ontruzant</b> (Samsung Bioepis/ Merck)	trastuzumab-dttb	150 mg vial (IV only)	1/18/ 2019	X	X	X
<b>Herceptin Hylecta</b> (Genentech)	trastuzumab; hyaluronidase -oysk	120 mg/2,000 units/mL (SC only)	2/28/2019	X	X	
<b>Trazimera</b> (Pfizer)	trastuzumab-qyyp	420 mg vial (IV only)	3/11/2019	X	X	X
<b>Kanjinti</b> (Amgen)	trastuzumab-anns	420 mg vial (IV only)	6/13/2019	X	X	X

Herceptin Hylecta, 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.

### Definitions and Measures

Adjuvant or adjunctive treatment: Treatment given after the primary treatment to increase the chances of a cure and may include chemotherapy, radiation, hormone or biological therapy.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Monoclonal antibody: A protein developed in the laboratory that can locate and bind to specific substances in the body and on the surface of cancer cells.

Targeted biologic agent: A newer type of drug developed specifically to target genetic changes in cells that cause cancer. It works differently than standard chemotherapy drugs, often with different side effects.

## Step Therapy

### Trastuzumab Reference and Biosimilar Agents Step Therapy

Requests for Herceptin (trastuzumab) may be approved when the following criteria is met:

- I. Individual has had a trial and intolerance to one preferred trastuzumab agent; **OR**  
Preferred agents: trastuzumab biosimilar agents (Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera).
- II. Individual is currently stabilized on Herceptin (trastuzumab).

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### HCPCS

<b>J9356</b>	Injection, trastuzumab, 10 mg and hyaluronidase-oysk (Herceptin Hylecta)
<b>J9355</b>	Injection, trastuzumab, excludes biosimilar, 10 mg
<b>Q5113</b>	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
<b>Q5117</b>	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg
<b>Q5114</b>	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
<b>Q5112</b>	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
<b>Q5116</b>	Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg

### ICD-10-CM

#### All Diagnosis

## Document History

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- 09/20/2021 – New document for Louisiana Medicaid.

## References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 16, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2021 National Comprehensive Cancer Network, Inc. Available at: [www.NCCN.org](http://www.NCCN.org). Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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