

Medical Drug Clinical Criteria

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 Hercessi, Herzuma, Ogivri, Ontruzant, Kanjinti, and Trazimera. 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
Herceptin (Genentech)	trastuzumab	150 mg/vial (IV only)	9/25/1998	X	X	X
Ogivri (Mylan/GMBH)	trastuzumab-dkst	150 mg/vial 420 mg/vial (IV only)	12/01/2017	X	X	X
Herzuma (Teva/Celltrion)	trastuzumab-pkrb	150 mg/vial 420 mg/vial (IV only)	12/14/2018	X	X	X
Ontruzant (Samsung Bioepis/Merck)	trastuzumab-dttb	150 mg/vial 420 mg/vial (IV only)	1/18/ 2019	X	X	X
Herceptin Hylecta (Genentech)	trastuzumab; hyaluronidase-oysk	120 mg/2,000 units/mL	2/28/2019	X	X	

		(SC only)				
Trazimera (Pfizer)	trastuzumab-qyyp	150 mg/ vial 420 mg vial (IV only)	3/11/2019	X	X	X
Kanjinti (Amgen)	trastuzumab-anns	150 mg vial 420 mg vial (IV only)	6/13/2019	X	X	X
Hercessi (Accord Biopharma)	Trastuzumab-strf	150 mg vial	04/05/2024	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.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Herceptin (trastuzumab) and trastuzumab biosimilars (Ogivri (trastuzumab-dkst); Herzuma (trastuzumab-pkrb); Ontruzant (trastuzumab-dttb); Trazimera (trastuzumab-qyyp); Hercessi (trastuzumab-strf); Kanjinti (trastuzumab-anns))

Requests for Herceptin (trastuzumab), Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp), Hercessi (trastuzumab-strf), or Kanjinti (trastuzumab-anns) may be approved.

Herceptin Hylecta (trastuzumab; hyaluronidase-oysk)

Requests for Herceptin Hylecta (trastuzumab; hyaluronidase-oysk) may be approved.

Step Therapy

Trastuzumab Reference and Biosimilar Agents Step Therapy

A list of the preferred trastuzumab agents is available [here](#).

Requests for a non-preferred trastuzumab agent may be approved when the following criteria is met:

- I. Individual has had a trial and intolerance to one preferred trastuzumab agent; **OR**

- II. Individual is currently stabilized on the requested non-preferred trastuzumab agent.

¹Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

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

<u>J9355</u>	<u>Injection, trastuzumab, excludes biosimilar, 10 mg [Herceptin]</u>
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk (Herceptin Hylecta)
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
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
Q5117	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg
Q5146	Injection, trastuzumab-strf (Hercessi), biosimilar, 10 mg

ICD-10-CM

All Diagnoses

Document History

Revised: 05/16/2025

Document History:

- 05/16/2025 – Annual Review: No Changes. Coding Reviewed: Updated description for HCPCS J9355.
- 12/11/2024 – Step therapy table updates.
- 06/10/2024 – Select Review: Update criteria to include new biosimilar Hercessi to PA and step therapy criteria. Wording and formatting updates. Coding Reviewed: Added HCPCS J3590. Added HCPCS Q5146 for Hercessi effective 1/1/2025 and deleted HCPCS J3590.
- 05/17/2024 – Annual Review: No Changes. Coding Reviewed: No changes.
- 08/15/2023 – Step therapy table updates.
- 05/19/2023 – Annual Review: No Changes. Coding Reviewed: No changes.
- 03/27/2023 – Step therapy table updates.
- 01/25/2023 – Step therapy table updates.
- 10/24/2022 – Step therapy table updates.
- 09/30/2022 – Step therapy table updates.
- 08/30/2022 – Step therapy table updates.
- 05/20/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 04/25/2022 – Step therapy table updates.
- 03/28/2022 – Step therapy table updates.
- 02/18/2022 – Step therapy table updates.
- 11/19/2021 – Select Review: Administrative update to clarify that trastuzumab agents may be approved. Coding reviewed: No changes.
- 05/21/2021 – Annual Review: No changes. Coding Changes: No changes.
- 12/21/2020 – Add step therapy for Medicaid line of business.
- 05/15/2020 – Annual Review: No changes. Coding Reviewed: Added HCPCS J9356, J9355, Q5113, Q5117, Q5114, Q5112, Q5116, All diagnosis pend

- 08/16/2019 – Annual Review: Add new NP step therapy for Herceptin Hylecta (trastuzumab; hyaluronidase). Add new NP step therapy for Trastuzumab biosimilar agents.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025 Updated periodically.
4. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2025 National Comprehensive Cancer Network, Inc. Available at: www.NCCN.org. Updated periodically.

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CC-0166 Trastuzumab Agents

Commercial Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
07/01/2022	Herceptin Kanjinti	Herzuma Ogivri Ontruzant Trazimera
01/01/2025	Herceptin Kanjinti	Herzuma Hercessi Ogivri Ontruzant Trazimera
04/01/2022 CalPERS For members 18 years and older, step therapy criteria applies to new starts only (defined as no use of Herceptin in the last 12 months)	Herzuma Kanjinti Ogivri Ontruzant Trazimera	Herceptin

Medicaid Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
10/1/2022: MD, NJ, NV, NY, SC, VA, WI, WNY 11/01/2022: AR, CA, GA, KY, LA 12/01/2022: IA, IN 02/01/2023: TN, OH 04/01/2023: DC	Kanjinti	Herceptin Herzuma Ogivri Ontruzant Trazimera

Medicare Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
07/01/2022	Herceptin Kanjinti	Herzuma Ogivri Ontruzant Trazimera