MED RX POLICY

POLICY: Oncology (Injectable) – Trastuzumab Products Med Rx Policy

- Herceptin® (trastuzumab intravenous infusion – Genentech)
- Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk subcutaneous injection – Genentech)
- Hercessi™ (trastuzumab-strf intravenous infusion – Accord BioPharma)
- Herzuma® (trastuzumab-pkrb intravenous infusion – Celltrion)
- Kanjinti® (trastuzumab-anns intravenous infusion – Amgen)
- Ogivri® (trastuzumab-dkst intravenous infusion – Mylan)
- Ontruzant® (trastuzumab-dttb intravenous infusion – Merck)
- Trazimera® (trastuzumab-qyyp intravenous infusion – Pfizer)

REVIEW DATE: 07/17/2024; selected revision 12/11/2024, 02/26/2025

OVERVIEW

Herzuma, Kanjinti, Ogivri, Ontruzant, Hercessi, and Trazimera are approved as biosimilars to Herceptin intravenous, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, and dosage form as Herceptin intravenous.[1-5,7] However, minor differences in clinically inactive components are allowed. Herceptin Hylecta is a combination of trastuzumab and hyaluronidase.[6] It is a different formulation and dosage form of trastuzumab (not a Herceptin biosimilar). The hyaluronidase component helps increase the absorption rate of trastuzumab into the systemic circulation.

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of the Preferred products. For all products (Preferred and Non-Preferred), the patient is required to meet the respective standard *Utilization Management Medical Policy* criteria. This program also directs the patient to try at least one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the respective standard *Utilization Management Medical Policy* criteria.

Automation: None.

Preferred Products: Kanjinti, Trazimera, Ogivri
Non-Preferred Products: Herceptin, Herceptin Hylecta, Herzuma, Ontruzant, Hercessi

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Herceptin Herzuma Ontruzant Hercessi	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology (Injectable) – Trastuzumab Products Utilization Management Medical Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried one of Kanjinti, Trazimera, or Ogivri; AND **ii.** Patient cannot continue to use the Preferred Product due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant], which according to the prescriber, would result in a significant allergy or serious adverse reaction.
Herceptin Hylecta	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology (Injectable) – Herceptin Hylecta Utilization Management Medical Policy* criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried one of Kanjinti, Trazimera, or Ogivri, but according to the prescriber, cannot continue to use this product; OR **ii.** Patient cannot continue on trastuzumab intravenous products due to an inability to obtain or maintain intravenous access; OR **iii.** Patient is currently taking the requested agent.

REFERENCES

1. Herceptin® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; Februrary 2021.
2. Herzuma® intravenous infusion [prescribing information]. North Wales, PA: Teva; May 2019.
3. Kanjinti® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; October 2019.
4. Ogivri® intravenous infusion [prescribing information]. Steinhausen, Switzerland: Mylan; October 2023.
5. Trazimera™ intravenous infusion [prescribing information]. New York, NY: Pfizer; November 2020.
6. Herceptin Hylecta™ subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; June 2024.
7. Ontuzant® intravenous infusion [prescribing information]. Whitehouse Station, NJ: Merck; March 2020.
8. Hercessi™ intravenous infusion [prescribing information]. Raleigh, NC: Accord BioPharma; September 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	No criteria changes	07/05/2023
Selected Revision	Moved Ogivri from Non-Preferred to Preferred Products. Adjusted exception criteria to note that patients could try one of Kanjinti, Trazimera, or Ogivri.	05/08/2024
Annual Revision	No criteria changes	07/17/2024
Selected Revision	Effective 01/01/2025: Added Hercessi to Non-Preferred Products.	12/11/2024
Selected Revision	Deleted continuation of therapy exception criteria for Herceptin, Herzuma, Ontruzant, and Hercessi.	02/26/2025