PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology (Injectable) – Trastuzumab Products Preferred Specialty Management Policy

- Herceptin® (trastuzumab intravenous infusion – Genentech)
- Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk subcutaneous injection – Genentech)
- Herzuma® (trastuzumab-pkrb injection 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: 06/29/2022

OVERVIEW

Herzuma, Kanjinti, Ogivri, Ontruzant, 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.[1-7] However, minor differences in clinically inactive components are allowed. At this time, the trastuzumab biosimilars have only demonstrated biosimilarity, not interchangeability. Herceptin Hylecta is a combination of trastuzumab and hyaluronidase. 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 Preferred Specialty Management program has been developed to encourage the use of the Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to the Preferred Products. Requests for Non-Preferred Products will be reviewed using the exception criteria (below). If the patient meets the standard *Oncology (Injectable) – Trastuzumab Products Prior Authorization Policy* OR *Oncology (Injectable) – Herceptin Hylecta Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Products will be authorized. All approvals are provided for a duration as directed in the respective *Standard Prior Authorization Policy* criteria.

Automation: None.

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

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Herceptin Herzuma Ogivri Ontruzant	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology (Injectable) – Trastuzumab Products PA Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried Kanjinti or Trazimera; AND **b)** 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; OR **ii.** Patient is currently taking the requested agent. **2.** For patients who have met the standard *Oncology (Injectable) – Trastuzumab Products PA Policy* criteria (1A), but have not met exception criteria (1B): approve the Preferred Products.
Herceptin Hylecta	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology (Injectable) – Herceptin Hylecta PA Policy* criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried Kanjinti or Trazimera 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 Herceptin Hylecta. **2.** For patients who have met the standard *Oncology (Injectable) – Herceptin Hylecta PA Policy* criteria (1A), but have not met exception criteria (1B): approve the Preferred Products.

REFERENCES

1. Herceptin® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; February 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; February 2021.
5. Trazimera™ intravenous infusion [prescribing information]. New York, NY: Pfizer; November 2020.
6. Herceptin Hylecta™ subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; February 2019.
7. Ontuzant® intravenous infusion [prescribing information]. Whitehouse Station, NJ: Merck; March 2020.