Reference number(s)
5269-D

This document applies to the following:

Product	Applies
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Trastuzumab Products

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the trastuzumab products specified in this document. Coverage for the non-preferred product is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Trastuzumab Products

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Kanjinti (trastuzumab-anns) • Ogivri (trastuzumab-dkst) • Ontruzant (trastuzumab-dttb)
Non-preferred	• Herceptin (trastuzumab) • Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) • Hercessi (trastuzumab-strf) • Herzuma (trastuzumab-pkrb) • Trazimera (trastuzumab-qyyp)

Step Therapy Criteria

Coverage for a non-preferred product is provided when either of the following criteria is met:

- Member has received treatment with the requested non-preferred product in the past 365 days.
- Member has had a documented intolerable adverse event to all of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc; June 2024.
2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
3. Hercessi [package insert]. Raleigh, NC: Accord BioPharma Inc.; September 2024.
4. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc; December 2024.
5. Trazimera [package insert]. New York, NY Pfizer Labs; November 2020.
6. Herzuma [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; December 2024.
7. Ogivri [package insert]. Cambridge, MA: Biocon Biologics Inc., November 2024.
8. Ontruzant [package insert]. Jersey City, NJ: Organon LLC; February 2025.