

## EXCEPTIONS CRITERIA TRASTUZUMAB PRODUCTS

### PREFERRED PRODUCTS: HERCEPTIN HYLECTA, HERZUMA, KANJINTI, OGIVRI, ONTRUZANT, AND TRAZIMERA

#### POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

#### I. PLAN DESIGN SUMMARY

This program applies to the trastuzumab products specified in this policy. Coverage for targeted products 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 members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

**Table. Trastuzumab Products**

	Product(s)
Preferred*	<ul style="list-style-type: none"><li>• <b>Herceptin Hylecta</b> (trastuzumab and hyaluronidase-oysk)</li><li>• <b>Herzuma</b> (trastuzumab-pkrb)</li><li>• <b>Kanjinti</b> (trastuzumab-anns)</li><li>• <b>Ogivri</b> (trastuzumab-dkst)</li><li>• <b>Ontruzant</b> (trastuzumab-dttb)</li><li>• <b>Trazimera</b> (trastuzumab-qyyp)</li></ul>
Targeted	<ul style="list-style-type: none"><li>• <b>Herceptin</b> (trastuzumab)</li></ul>

\*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

#### II. EXCEPTION CRITERIA

Coverage for the targeted product is provided when either of the following criteria is met:

- A. Member has received treatment with the targeted product in the past 365 days
- B. Member has had a documented intolerable adverse event to at least three 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; February 2021.
2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
3. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc; October 2019.
4. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2020.
5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc; May 2019.
6. Ogivri [package insert]. Steinhausen, Switzerland: Mylan GmbH; February 2021.
7. Ontruzant [package insert]. Whitehouse Station, NJ: Merk Sharp & Dohme Corp.; March 2020.

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