

This policy applies to the following:

✓	Standard Control (SF)	✓	Value (VF)		ACSF Chart (ACSFC)	✓	Medical Benefit		Medicare Part B
✓	Standard Control Choice (SCCF)		Managed Medicaid Template (MMT)		SF Chart (SFC)		Medical Benefit: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
✓	Advanced Control Specialty (ACSF)		New to Market (NTM)		IVL		Medical Benefit: Add-on		
✓	Advanced Control Specialty for Choice (ACSCF)		Aetna Health Exchange (AHE)						

Reference #
3506-D

## EXCEPTIONS CRITERIA TRASTUZUMAB PRODUCTS

### PREFERRED PRODUCTS: HERZUMA AND OGIVRI

#### 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 all members requesting treatment with a targeted product.

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

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

#### II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when the member has had a documented intolerable adverse event to both 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).

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## **REFERENCES**

1. Herceptin [package insert]. South San Francisco, CA: Genetech, Inc; February 2021.
2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
3. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc; May 2019.
4. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc; October 2022.
5. Ogivri [package insert]. Steinhausen, Switzerland: Mylan GmbH; July 2023.
6. Ontruzant [package insert]. Whitehouse Station, NJ: Merk Sharp & Dohme Corp.; June 2021.
7. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2020.