

This policy applies to the following:

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

Reference #
4671-D

EXCEPTIONS CRITERIA TRASTUZUMAB PRODUCTS

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

*: 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 either of the following criteria is met:

- A. Member has received treatment with the requested 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).

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	Value (VF)	Aetna Health Exchange (AHE)		Medical Benefit: Managed Medicaid	
		IVL			

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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 2022.
4. Trazimera [package insert]. New York, NY: Pfizer Labs; November 2020.
5. Herzuma [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; May 2019.
6. Ogivri [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2021.
7. Ontruzant [package insert]. Jersey City, NJ: Organon LLC.; June 2021.