This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4671-D

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*	• **Herceptin Hylecta** (trastuzumab and hyaluronidase-oysk) • **Herzuma** (trastuzumab-pkrb) • **Kanjinti** (trastuzumab-anns) • **Ogivri** (trastuzumab-dkst) • **Ontruzant** (trastuzumab-dttb) • **Trazimera** (trastuzumab-qyyp)
Targeted	• **Herceptin** (trastuzumab)

*: 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

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**		**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
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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. 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.