MetroPlus Health

Policy and Procedure

Title: UM-PT012 Trastuzumab	**Division: Medical Management** **Department: Pharmacy**
Approval Date: 4/28/2023	**LOB: Medicaid, HIV SNP, HARP, QHP, EP, Gold, GoldCare, CHP**
Effective Date: 4/28/2023	**Policy Number: UM-PT012**
Review Date: 3/4/2026	**Cross Reference Number:**
Retired Date:	**Page 1 of 4**

I. POLICY DESCRIPTION:

Monoclonal antibody - Herceptin (Trastuzumab), Herzuma (Trastuzumab-pkrb), Kanjinti (Trastuzumab-anns), Ogivri (Trastuzumab-dkst), Ontruzant (Trastuzumab-ddtb), and Trazimera (Trastuzumab-qyyp)

Monoclonal antibody - Trastuzumab	
Preferred	Herzuma (trastuzumab-pkrb, biosimilar, 10 mg) Kanjinti (trastuzumab-anns, biosimilar, 10 mg) Ogivri (trastuzumab-dkst, biosimilar, 10 mg) Ontruzant (trastuzumab-dttb, biosimilar, 10 mg) Trazimera (trastuzumab-qyyp, biosimilar, 10 mg)
Non-preferred	Herceptin (trastuzumab, excludes biosimilar, 10 mg)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Trastuzumab is a monoclonal antibody which binds to the extracellular domain of the human epidermal growth factor receptor 2 protein (HER-2); it mediates antibody-dependent cellular cytotoxicity by inhibiting proliferation of cells which overexpress HER-2 protein

IV. POLICY:

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

Non-preferred drugs will be approved when ALL of the following criteria are met:

A. ONE of the following:
- **a.** Documented trial and failure with ALL preferred agents listed above;

OR
- **b.** The preferred agents are not appropriate for the member and clinical rationale is provided;

AND

B. Indication, dose, frequency and duration is in accordance with FDA label or compendial supported

AND

C. Authorization is for no more than 12 months

V. LIMITATIONS/ EXCLUSIONS:

Herceptin, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera is considered to be experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg

VII. REFERENCES:

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
2. Kanjinti [package insert]. Thousand Oaks, CA: Amgen, Inc.; October 2022.
3. Ogivri [package insert]. Zurich, Switzerland: Mylan GmbH; July 2023.
4. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2020.
5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc. May 2019.
6. Ontruzant [package insert]. Whitehouse Station, NJ: Merck. June 2021.
7. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 17, 2023.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2023. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed April 17, 2023.
9. Thorpe LM, Schrock AB, Erlich RL, et al. Significant and durable clinical benefit from trastuzumab in 2 patients with HER2-amplified salivary gland cancer and a review of the literature. Head Neck. 2017;39(3): E40-E44.
10. Rugo HS, Barve A, Waller CF, et al. Effect of a Proposed Trastuzumab Biosimilar Compared With Trastuzumab on Overall Response Rate in Patients With ERBB2 (HER2)–Positive Metastatic Breast Cancer A Randomized Clinical Trial. JAMA. 2017;317(1):37–47.
11. Pivot X, Bondarenko I, Nowecki Z, et al. Phase III, Randomized, Double-Blind Study Comparing the Efficacy, Safety, and Immunogenicity of SB3 (Trastuzumab Biosimilar) and Reference Trastuzumab in Patients Treated With Neoadjuvant Therapy for Human Epidermal Growth Factor Receptor 2–Positive Early Breast Cancer. J Clin Oncol. 2018; 36(10): 968 – 74.

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REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	SC	4/28/2023
Update	AKC	11/28/2023
Update	AKC	5/29/2024
Annual Review	JL	3/4/2026

Approved: **Date:**	**Approved:** **Date:**
Suzana Patel 3/12/26	03.12.2026
Suzana Patel, PharmD **Senior Director of Pharmacy**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.

MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.