Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Medical Benefit Drugs

Trastuzumab Products: Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA)-Approved Indications

Herceptin (trastuzumab) is a HER2/neu receptor antagonist indicated for the treatment of the following types of cancers:

Adjuvant Breast Cancer

- Adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; as part of a treatment regimen with docetaxel and carboplatin; and as a single agent following multi-modality anthracycline based therapy

Metastatic Breast Cancer

- In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

Metastatic Gastric Cancer

- In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease

Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, indicated:

Adjuvant Breast Cancer

- For adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; as part of a treatment regimen with docetaxel and carboplatin; and as a single agent following multi-modality anthracycline based therapy

Metastatic Breast Cancer

- In adults in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-over expressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

Kanjinti (trastuzumab-anns) and Trazimera (trastuzumab-qyyp) are the preferred trastuzumab products and are available without prior authorization.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Ogivri, or Ontruzant for Members when **ALL** of the following criteria are met:

1. Documented previous failure of or clinical inappropriateness of treatment with Kanjinti or Trazimera

Off-label Use Coverage for Other Cancer Diagnoses

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the “Sullivan Law”: (M.G.L. c.175, s.47K).

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

Note: The plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, The plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other “Standard Reference Compendia” noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.

"Standard Reference Compendia"

1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

"Peer Reviewed Medical Literature"

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

of Cancer and Clinical Oncology)

When the plan evaluates the evidence in published, peer-reviewed medical literature, consideration will be given to the following:

1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question.
    a. whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question (e.g., in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trial s, placebos, or crossover);
    b. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
    c. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Limitations

- Coverage of Herceptin, Herceptin Hylecta, Herzuma, Ogivri, or Ontruzant will be authorized for any FDA-approved indication that preferred trastuzumab biosimilars do not share.
- Documentation of any previous use of Herceptin, Herceptin Hylecta, Herzuma, Ogivri, or Ontruzant does not qualify as a clinically appropriate reason to not prescribe preferred biosimilars.
- Authorizations will be provided for 12 months.
- Step therapy, or first-fill requirements not required when the patient lives in or the prescribing provider's office is located in Maine for the treatment of metastatic cancer and associated conditions.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase -oysk
Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg
Q5114	Injection, trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5146	Injection, trastuzumab-strf (Hercessi), biosimilar, 10 mg

References

1. Herceptin (trastuzumab) [prescribing information]. South San Francisco, CA: Genentech, Inc.; February 2021.
2. Herceptin Hylecta (trastuzumab and hyaluronidase -oysk) [prescribing information]. South San
3. Francisco, CA: Genentech, Inc.; February 2019.
4. Herzuma (trastuzumab-pkrb) [prescribing information]. North Wales, PA. Teva Pharmaceuticals, USA Inc. May 2019.
5. Hercessi (trastuzumab-strf) [prescribing information]. Raleigh, NC: Accord BioPharmac Inc.; September 2024.
6. Kanjinti (trastuzumab-anns) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; October 2019
7. Ogivri (trastuzumab-dkst) [prescribing information]. Steinhausen, Switzerland: Mylan GmbH; February 2021.
8. Ontruzant (trastuzumab-dttb) [prescribing information]. North Wales, PA; Teva Pharmaceuticals. May 2019.
9. Trazimera (trastuzumab-qyyp) [prescribing information]. New York, NY: Pfizer Inc.; March 2019.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: Moved Ogivri to non-preferred status. Updated criteria to “Documented previous failure of or clinical

inappropriateness of treatment with Kanjinti or Trazimera." Coverage for Tufts Health Together and Tufts Health RITogether apply to Medical Necessity Guideline (effective 1/1/2024).

- September 10, 2024: No changes (eff 9/10/24).
- September 2024: Administrative Update: Rebranded from Tufts Health Unify to Tufts Health One Care.
- December 10, 2024: Added Hercessi to the Medical Necessity Guideline (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- November 4, 2025: Effective January 1, 2026, added limitation pertaining to patient or prescribing provider's office is located in Maine to support LD 178 - An Act Regarding Coverage for Step Therapy for Metastatic Cancer.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.