Mass General Brigham
Health Plan

Herceptin Products
Herceptin (trastuzumab)
Herceptin Hylecta (trastuzumab-hyaluronidase-oysk)
Hercessi (trastuzumab-strf)
Herzuma (trastuzumab-pkrb)
Kanjinti (trastuzumab-anns)
Ogivri (trastuzumab-dkst)
Ontruzant (trastuzumab-dttb)
Trazimera (trastuzumab-qyyp)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Herceptin (trastuzumab) is a HER2/neu receptor antagonist that is Food and Drug administration (FDA)-approved for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or GEJ adenocarcinoma. The Herceptin (trastuzumab) biosimilars (Herzuma [trastuzumab-pkrb], Kanjinti [trastuzumab-anns], Ogivri [trastuzumab-dkst], Ontruzant [trastuzumab-dttb], and Trazimera [trastuzumab-qyyp]) have the same exact FDA-approved indications as the reference product.

The National Comprehensive Cancer Network (NCCN) guidelines for the treatment of breast, gastric, and gastroesophageal cancers support the use of Herceptin (trastuzumab) for HER2-positive disease according to the FDA-labeling. In addition, the NCCN indicates that an FDA-approved biosimilar is an appropriate substitute for the reference product.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

Breast Cancer
1. Diagnosis of HER2-overexpressing breast cancer
2. Prescriber is an oncologist

3. Appropriate dosing (*weight required)*
4. For Herceptin (trastuzumab), Hercessi (trastuzumab-strf), Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp), medical records documenting **BOTH** of the following:
    a. Inadequate response, adverse reaction, or contraindication to Kanjinti (trastuzumab-anns)
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agent

Metastatic Gastric or GEJ Adenocarcinoma

1. Requested agent is ONE of the following:
    a. Herceptin (trastuzumab)
    b. Hercessi (trastuzumab-strf)
    c. Herzuma (trastuzumab-pkrb)
    d. Kanjinti (trastuzumab-anns)
    e. Ogivri (trastuzumab-dkst)
    f. Ontruzant (trastuzumab-dttb)
    g. Trazimera (trastuzumab-qyyp)
2. Diagnosis of HER2-overexpressing metastatic gastric or GEJ adenocarcinoma
3. Prescriber is an oncologist
4. Appropriate dosing (*weight required)*
5. Requested agent will be used in combination with chemotherapy
6. For Herceptin (trastuzumab), Hercessi (trastuzumab-strf), Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp), medical records documenting **BOTH** of the following:
    a. Inadequate response,adverse reaction, or contraindication to Kanjinti (trastuzumab-anns)
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agent

Unresectable or Metastatic Colorectal Cancer

1. Requested agent is ONE of the following:
    a. Herceptin (trastuzumab)
    b. Hercessi (trastuzumab-strf)
    c. Herzuma (trastuzumab-pkrb)
    d. Kanjinti (trastuzumab-anns)
    e. Ogivri (trastuzumab-dkst)
    f. Ontruzant (trastuzumab-dttb)
    g. Trazimera (trastuzumab-qyyp)
2. Diagnosis of RAS wild-type (WT), HER2-positive unresectable or metastatic colorectal cancer
3. Prescriber is an oncologist
4. Appropriate dosing (*weight required)*
5. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following regimens *(see Appendix of commonly used regimens):*
    a. CAPEOX
    b. FOLFOX
    c. FOLFIRI
    d. FOLFOXIRI
    e. FOLFIRINOX
    f. irinotecan-based therapy

    g. oxaliplatin-based therapy
6. Requested agent will be used in combination with Tukysa (tucatinib)
7. For Herceptin (trastuzumab), Hercessi (trastuzumab-strf), Herzuma (trastuzumab-pkrb), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp), medical records documenting BOTH of the following:
    a. Inadequate response,adverse reaction, or contraindication to Kanjinti (trastuzumab-anns)
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agent

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months

Appendix

Components of Commonly Used Regimens for Treatment of Colorectal Cancer

Regimen Abbreviation	Drug Components
CAPEOX	capecitabine/oxaliplatin
FOLFIRI	leucovorin calcium (folinic acid)/fluorouracil/irinotecan
FOLFOX	leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin
FOLFOXIRI	leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin/irinotecan
FOLFIRINOX	leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin/irinotecan

References

1. Herceptin (trastuzumab) [package insert]. South San Francisco (CA): Genentech, Inc; 2024 Nov.
2. Herzuma (trastuzumab-pkrb) [prescribing information]. North Wales (PA); Celltrion, Inc; 2025 Feb.
3. Kanjinti (trastuzumab-anns) [prescribing information]. Thousand Oak (CA): Amgen, Inc.; 2024 Dec.
4. Ogivri (trastuzumab-dkst) prescribing information. Rockford (IL); Mylan; 2024 Nov.
5. Ontruzant (trastuzumab-dttb) prescribing information. Whitehouse Station (NJ); Merck & Co, Inc; 2024 Mar.
6. Trazimera (trastuzumab-qyyp) [package insert]. New York (NY): Pfizer; 2024 Dec.
7. NCCN. Clinical Practice Guidelines in Oncology for Breast Cancer. Version 4.2021; 2021 April 28 [cited 2021 May 7]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf.
8. Herceptin (trastuzumab and hyaluronidase-oysk [package insert]. South San Francisco (CA): Genentech Inc; 2014 Nov.
9. Hercessi (trastuzumab-strf) prescribing information. Raleigh (NC): Accord BioPharma Inc; 2024 Sep.
10. NCCN. Clinical Practice Guidelines in Oncology for Gastric Cancer. Version 2.2026; 2026 Jan 21 [cited 2026 Feb 20]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf.
11. NCCN. Clinical Practice Guidelines in Oncology for Esophageal and Esophagogastric Junction Cancers. Version 2.2026; 2026 Jan 21 [cited 2026 Feb 20]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf

Review History

01/30/2022 - Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

07/12/23 – Reviewed and updated for P&T. Expanded indication for use of Tukysa(tucatinib) to be used in combination with trastuzumab for the treatment of adult patients with RAS wild-type (WT), HER2-positive unresectable or metastatic colorectal cancer (mCRC) that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Brand preferred and mandatory generic language was added under Limitations. Effective 7/31/23
06/11/25 – Reviewed and updated for P&T. Updated formatting and references. Added new biosimilar, Hercessi, to criteria. Effective 7/1/25
07/15/26 – Reviewed and updated for P&T. Kanjinti added as step-through trial for other products. Effective 8/10/26
11/4/26 – Reviewed and updated for P&T. Clarified language for clinical rationale requirement. Updated formatting and references. Effective 1/4/27