Mass General Brigham
Health Plan

Herceptin Products
Effective 07/31/2023

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

No PA	Drugs that require PA
Please refer to the NCCN guidelines	Herceptin® (trastuzumab)
	Herceptin Hylecta® (trastuzumab-hyaluronidase-oysk)
	Herceptin® Biosimilars that require PA
	Herzuma® (trastuzumab-pkrb)
	Kanjinti® (trastuzumab-anns)
	Ogivri® (trastuzumab-dkst)
	Ontruzant® (trastuzumab-dttb)
	Trazimera® (trastuzumab-qyyp)

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Breast Cancer
ALL of the following:
1. Diagnosis of HER2-overexpressing breast cancer
2. Prescriber is an oncologist
3. Appropriate dosing (*weight required)*

Metastatic Gastric or GEJ Adenocarcinoma

ALL of the following:

1. Requested agent is one of the following:
    a. Herceptin® (trastuzumab)
    b. Herzuma® (trastuzumab-pkrb)
    c. Kanjinti® (trastuzumab-anns)
    d. Ogivri® (trastuzumab-dkst)
    e. Ontruzant® (trastuzumab-dttb)
    f. 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

Unresectable or Metastatic Colorectal Cancer

ALL of the following:

1. Requested agent is one of the following:
    a. Herceptin® (trastuzumab)
    b. Herzuma® (trastuzumab-pkrb)
    c. Kanjinti® (trastuzumab-anns)
    d. Ogivri® (trastuzumab-dkst)
    e. Ontruzant® (trastuzumab-dttb)
    f. 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)

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
2. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).

3. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.

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

Approved Dosing

Herceptin® (trastuzumab) Herzuma® (trastuzumab-pkrb) Kanjinti® (trastuzumab-anns) Ogivri® (trastuzumab-dkst) Ontruzant® (trastuzumab-dttb) Trazimera® (trastuzumab-qyyp)	**Adjuvant breast cancer:** - Initial dose of 4 mg/kg, then 2 mg/kg weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel/carboplatin). One week after the last weekly dose, administer 6 mg/kg every three weeks to complete a total of 52 weeks of therapy - Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg every three weeks for 52 weeks **Metastatic breast cancer**: - Initial dose of 4 mg/kg followed by subsequent weekly doses of 2 mg/kg **Metastatic gastric cancer**: - Initial dose of 8 mg/kg, followed by 6 mg/kg every 3 weeks
Herceptin Hylecta® (trastuzumab-hyaluronidase-oysk)	**Breast cancer**: - 600 mg/10,000 units (600 mg trastuzumab and 10,000 units hyaluronidase) once every three weeks

References

1. Herceptin® (trastuzumab) [package insert]. South San Francisco (CA): Genentech, Inc; 2021 Feb.
2. Herzuma® (trastuzumab-pkrb) [prescribing information]. North Wales (PA); Celltrion, Inc; 2019 May.
3. Kanjinti® (trastuzumab-anns) [prescribing information]. Thousand Oak (CA): Amgen, Inc.; 2019 Oct.
4. Ogivri® (trastuzumab-dkst) prescribing information. Rockford (IL); Mylan; 2021 Feb.
5. Ontruzant® (trastuzumab-dttb) prescribing information. Whitehouse Station (NJ); Merck & Co, Inc; 2020 Mar.

6. Trazimera® (trastuzumab-qyyp) [package insert]. New York (NY): Pfizer; 2020 Nov.
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; 2019 Feb.

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