Clinical Policy Title:	trastuzumab
Policy Number:	RxA.674
Drug(s) Applied:	Herceptin Hylecta™
Original Policy Date:	03/09/2021
Last Review Date:	09/04/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Member has a diagnosis of HER2 positive breast cancer or leptomeningeal metastases from HER2 positive breast cancer;
2. Member must meet one or more of the following (a, b, c, d, or e):
   a. As a component of neoadjuvant therapy prior to surgical treatment;
   b. As adjuvant treatment to complete a 12-month (52 week) course of trastuzumab;
   c. As treatment of metastatic breast cancer, as monotherapy or in combination with a chemotherapy regimen that is recognized by ASCO or NCCN;
   d. In combination with lapatinib as treatment of metastatic breast cancer when both of the following criteria are met (i and ii):
      i. Member has received or is receiving trastuzumab-based therapy; and
      ii. Disease has progressed on or after trastuzumab;
   e. In combination with pertuzumab when the following criteria are met (i, ii, and iii):
      i. Breast tumor is HER2 positive;
      ii. Trastuzumab is used in combination with pertuzumab and either docetaxel or paclitaxel, unless contraindicated;
      iii. The combination therapy with pertuzumab will be used as a single line anti-HER2 chemotherapy for metastatic breast cancer until disease progression.

Approval Duration
All lines of business (except Medicare): 6 months

B. Gastric, Esophageal and Gastroesophageal Adenocarcinoma (must meet all)**:**

1. Member has a diagnosis of HER2 positive advanced gastric, esophageal or gastroesophageal junction adenocarcinoma;
2. Must be used in combination with cisplatin and either capecitabine or 5-fluorouracil.

Approval Duration
All lines of business (except Medicare): 6 months

C. Colorectal Cancer (off-label) (must meet all)**:**

1. Member has a diagnosis of HER2 positive, wild-type RAS, advanced or metastatic colorectal cancer;
2. Member has not been treated with previous HER2 inhibitor therapy (e.g., trastuzumab, ado-

trastuzumab emtansine, lapatinib, pertuzumab);
3. Must be used in combination with pertuzumab or lapatinib.

Approval Duration
All lines of business (except Medicare): 6 months

D. Endometrial Carcinoma (off-label) (must meet all)**:**
1. Member has a diagnosis of advanced (i.e., stage III/IV) or recurrent HER2 positive endometrial carcinoma;
2. Must be prescribed in combination with carboplatin and paclitaxel;

Approval Duration
All lines of business (except Medicare): 6 months

E. Salivary Gland Cancer (off-label) (must meet all)**:**
1. Member has a diagnosis of recurrent, unresectable or metastatic HER2 positive salivary gland carcinoma;
2. Prescribed as monotherapy or in combination with docetaxel or pertuzumab;

Approval Duration
All lines of business (except Medicare): 6 months

F. Central Nervous System Cancer (off-label) (must meet all)**:**
1. Member has a diagnosis of limited and extensive brain metastases with HER2 positive breast cancer;
2. Prescribed in combination with capecitabine and tucatinib;
3. Previously treated with at least one anti-HER2-based regimens unless contraindicated or clinically significant adverse effect are experienced;

Approval Duration
All lines of business (except Medicare): 6 months

G. Hepatobiliary Cancers (off-label) (must meet all)**:**
1. Member has a diagnosis of any one of the following hepatobiliary cancers (a or b);
   a. Cholangiocarcinoma (Intrahepatic/ Extrahepatic);
   b. Gallbladder Cancer;
2. Disease is unresectable or metastatic;
3. The request is for Herceptin®;
4. Prescribed as subsequent treatment in combination with pertuzumab for progression on or after systemic treatment.

Approval Duration
All lines of business (except Medicare): 6 months

II. Continued Therapy Approval

A. All indications listed in section I (must meet all):
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All lines of business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Breast Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 4, 2024.

2. National Comprehensive Cancer Network. Central Nervous System Cancers Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 4, 2024.
3. National Comprehensive Cancer Network. Colon Cancer Version 5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed September 4, 2024.
4. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed September 4, 2024.
5. National Comprehensive Cancer Network. Gastric Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed September 4, 2024.
6. National Comprehensive Cancer Network. Head and Neck Cancers Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed September 4, 2024.
7. National Comprehensive Cancer Network. Rectal Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed September 4, 2024.
8. National Comprehensive Cancer Network. Uterine Neoplasms Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed September 4, 2024.
9. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed September 4, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/23/2020	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, I.D.4: Updated to include drugs trastuzumab must be prescribed with for endometrial carcinoma. 2. Initial Approval Criteria, I.F: Updated to include approval criteria for indication, Central Nervous System Cancer. 3. References were reviewed and updated.	12/13/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B.4, I.C.4, I.D.4, I.E.4, I.F.4: Updated to include new drug specific criteria The request for any one of the following: Herceptin®, Herzuma®, Kanjinti™, Ogivri®, Ontruzant®, Trazimera™. 2. Initial Approval Criteria, I.G: Updated to include approval criteria for indication, Hepatobiliary Cancers. 3. References were reviewed and updated.	10/27/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023

Policy was reviewed: 1. Removed Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera from policy	03/15/2024	02/28/2024
Policy was reviewed: 1. Reviewed age, dosing, and prescriber requirements. 2. Removed reauthorization requirement for positive response to therapy. 3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 4. References were reviewed and updated.	09/04/2024	09/13/2024