

<b>Clinical Policy Title:</b>	trastuzumab
<b>Policy Number:</b>	RxA.674
<b>Drug(s) Applied:</b>	Herceptin Hylecta™
<b>Original Policy Date:</b>	03/09/2021
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	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-

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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](https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf). Accessed September 4, 2024.

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9. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 1.2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/hepatobiliary.pdf](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: <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.D.4: Updated to include drugs trastuzumab must be prescribed with for endometrial carcinoma.</li> <li>2. Initial Approval Criteria, I.F: Updated to include approval criteria for indication, Central Nervous System Cancer.</li> <li>3. References were reviewed and updated.</li> </ol>	12/13/2021	01/17/2022
Policy was reviewed: <ol style="list-style-type: none"> <li>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™.</li> <li>2. Initial Approval Criteria, I.G: Updated to include approval criteria for indication, Hepatobiliary Cancers.</li> <li>3. References were reviewed and updated.</li> </ol>	10/27/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera from policy</li> </ol>	03/15/2024	02/28/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Reviewed age, dosing, and prescriber requirements.</li> <li>2. Removed reauthorization requirement for positive response to therapy.</li> <li>3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>4. References were reviewed and updated.</li> </ol>	09/04/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025