UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – HER2 Antagonist) – Herceptin Hylecta Utilization Management Medical Policy
- Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk subcutaneous injection – Genentech)

REVIEW DATE: 03/05/2025

OVERVIEW

Herceptin Hylecta is indicated for the following uses:[1]

- **Breast Cancer, adjuvant treatment** in tumors with human epidermal growth factor receptor 2 (HER2) overexpressing node positive or node negative (estrogen receptor [ER]-/progesterone receptor [PR]-negative or with one high risk feature) breast cancer in adults:
  - 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.
  - As a single agent following multi-modality anthracycline based therapy.
- **Breast Cancer**, metastatic, in adults with HER2-overexpressing disease:
  - In combination with paclitaxel for first-line treatment.
  - As a single agent for the treatment of patients who have received one or more chemotherapy regimens for metastatic disease.

Guidelines

The National Comprehensive Cancer Network (NCCN) breast cancer clinical practice guidelines (version 1.2025 – January 31, 2025) state that Herceptin Hylecta may be substituted for trastuzumab intravenous and used as a single-agent or in combination with other systemic therapies.[2,3] The guidelines note the different dose and dosage form of Herceptin Hylecta compared with trastuzumab. It is also noted that Herceptin Hylecta cannot be substituted for Kadcyla™ (ado-trastuzumab emtansine intravenous infusion) or Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion). Trastuzumab is recommended as part of a preferred regimen in the preoperative, adjuvant, and metastatic setting for HER2-positive disease.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Herceptin Hylecta. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Herceptin Hylecta, as well as the monitoring required for adverse events and long-term efficacy, approval requires Herceptin Hylecta to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Herceptin Hylecta is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Breast Cancer**. Approve for the duration noted below if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Approve for up to 1 year (total) if the medication is used for adjuvant treatment; OR
     - **ii.** Approve for 1 year if the medication is used for recurrent or metastatic disease; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve 600 mg/10,000 units (600 mg trastuzumab and 10,000 units hyaluronidase) Herceptin Hylecta administered subcutaneously once every three weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Herceptin Hylecta is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Herceptin Hylecta™ subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; June 2024.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 3, 2025.
3. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 3, 2025. Search term: Herceptin Hylecta.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/22/2023
Annual Revision	No criteria changes.	03/20/2024
Annual Revision	No criteria changes.	03/05/2025
Update	04/21/2025: The policy name was changed from "Oncology (Injectable) - Herceptin Hylecta UM Medical Policy" to "Oncology (Injectable - HER2 Antagonist) - Herceptin Hylecta UM Medical Policy"	N/A

N/A – Not applicable.