Utilization Review Policy 163A

POLICY: Oncology – Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk for subcutaneous use – Genentech Inc.)

EFFECTIVE DATE: 7/1/2021
LAST REVISION DATE: 05/07/2025

COVERAGE CRITERIA FOR: UCare Medical Assistance and Exchange Plans Only (PMAP, Connect, MSC+, MnCare, all Individual and Family Plans)

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:
  - **a)** As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel.
  - **b)** As part of a treatment regimen with docetaxel and carboplatin.
  - **c)** As a single agent following multi-modality anthracycline based therapy.
- **Breast Cancer**, metastatic, in adults with HER2-overexpressing disease:
  - **a)** In combination with paclitaxel for first-line treatment.
  - **b)** 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 2.2024 – March 11, 2024) 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 for request meeting both the preferred product step therapy requirements and indication requirements.

Preferred Product(s): Kanjinti, Trazimera, Ogivri
Non-Preferred Products(s): Herceptin Hylecta

Step Therapy Requirements:

Authorization for a non-preferred biologic product or biosimilar will be granted if the patient has had *any one of the listed issues below (A, B, C, or D) with all preferred product(s). Chart notes documenting* the issue must be provided at time of request:

A. Allergic reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR

B. Adverse reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR

C. Therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure during an adequate trial of all preferred biologic products or biosimilars which allowed sufficient time for a positive treatment outcome documented by medical chart notes OR

D. The patient has a diagnosis not included in the FDA-approved indications of all preferred products, but is included in the FDA-approved indications of the non-preferred product

Please note:

- Factors such as patient or prescriber preference or healthcare facility's or pharmacy's inability or unwillingness to order or stock the preferred product(s) will not be considered
- Common side effects to all products and infusion-related reactions are not considered documented allergic reactions to a preferred product as they would be expected with the innovator and biosimilar products
- Continuation of therapy overrides are not available to bypass required trial(s) of preferred biosimilar or biologic reference product

- Generally, an adequate trial of a drug is considered to be three months or longer in order to allow time for efficacy to be established

FDA-Approved Indications

1. **Breast Cancer**. Approve for the duration noted below if the patient meets ALL of the criteria (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 criteria (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™ for subcutaneous use [prescribing information]. South San Francisco, CA: Genentech, Inc.; February 2019.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 1.2019 – March 14, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 18, 2019.
3. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 18, 2019. Search term: trastuzumab hyaluronidase.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Breast Cancer:** Added age criterion for approval.	03/17/2021
Annual Revision	**Breast Cancer:** "Recurrent" was added to the criteria that the patient has metastatic disease	03/30/2022
Annual Revision	No criteria changes	03/22/2023
Annual Revision	No criteria changes	03/20/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	03/05/2025
UCare Revision	Added Ogivri as a preferred trastuzumab product along with Kanjinti and Trazimera.	4/30/2025

UCare Update	Updated step therapy criteria to require clinical need for non-preferred product over the preferred products including chart note documentation to support the need for a non-preferred product.	05/07/2025