PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Herceptin Hylecta Prior Authorization Policy
- Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk subcutaneous injection – Genentech)

REVIEW DATE: 03/30/2022

OVERVIEW

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

- **Breast Cancer, adjuvant treatment** of adults 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:
  - **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 2.2022 – December 20, 2021) 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 prescription benefit coverage of Herceptin Hylecta. 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 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.

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; February 2019.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 24, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 22, 2022. Search term: Herceptin Hylecta.