

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

DATE REVIEWED: 03/25/2020

OVERVIEW

Herceptin Hylecta is indicated in breast cancer for the following uses¹:

- 1) 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.
- 2) Metastatic breast cancer 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 NCCN Breast Cancer clinical practice guidelines (version 3.2020 – March 6, 2020) recommend substitution of Herceptin Hylecta for trastuzumab intravenous (IV) in the treatment algorithm.^{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 Kadcylla™ (ado-trastuzumab emtansine for intravenous injection). Trastuzumab is recommended as part of a preferred regimen in the preoperative/adjuvant therapy setting in HER2-positive disease. As part of a preferred regimen, it can be used in combination with doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab ± Perjeta® (pertuzumab for injection); paclitaxel + trastuzumab; and docetaxel/carboplatin/trastuzumab ± Perjeta. Docetaxel + cyclophosphamide + trastuzumab is noted under “useful in certain circumstances.” Other recommended regimens are doxorubicin/cyclophosphamide followed by docetaxel + trastuzumab ± Perjeta. If there is no residual disease after preoperative therapy or no preoperative therapy: complete up to one year of HER2-targeted therapy with trastuzumab (category 1) ± Perjeta. If there is residual disease after preoperative therapy: Kadcylla alone (category 1) is preferred. If Kadcylla is discontinued for toxicity, then trastuzumab (category 1) ± Perjeta can be used to complete 1 year of therapy. For systemic treatment of recurrent or stage IV (M1) disease that is hormone-receptor positive and HER2-positive, trastuzumab + Perjeta + taxane is preferred; or trastuzumab + chemotherapy; or Kadcylla can be used; or endocrine therapy ± HER2-targeted therapy. For HER2-positive disease and postmenopausal and premenopausal patients endocrine therapy options include, aromatase inhibitor ± trastuzumab; aromatase inhibitor + trastuzumab ± Tykerb® (lapatinib tablets); Faslodex (fulvestrant for injection) ± trastuzumab, tamoxifen ± trastuzumab (all category 2A). For premenopausal patients, ovarian ablation or suppression is recommended in addition to endocrine therapy ± trastuzumab.

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(s). 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 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, initial approval requires Herceptin Hylecta to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Breast Cancer.** Approve for the duration noted below if the patient meets ALL of the criteria (A, B, and C):
 - A)** The patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
 - B)** The 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 metastatic disease; AND
 - C)** 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

Herceptin Hylecta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

- 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 3.2020 – March 6, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 16, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 16, 2020. Search term: trastuzumab hyaluronidase.

HISTORY

Type of Revision	Summary of Changes*	Date Reviewed
New policy	--	03/20/2019
Update	03/31/2019: For clarity, in the Breast Cancer indication added “for the duration noted below” to look for different approval durations. Also, deleted “Breast Cancer – Adjuvant Treatment for Greater than 1 year” from Conditions Not Recommended for Approval, since this is already being addressed with the limited approval duration within criteria.	--
Annual revision	No criteria changes	03/25/2020