Reference number(s)
4615-A

STANDARD MEDICARE PART B MANAGEMENT

HERCEPTIN HYLECTA (trastuzumab and hyaluronidase-oysk)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Herceptin Hylecta is indicated for adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer:
      i. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      ii. As part of a treatment regimen with docetaxel and carboplatin
      iii. As a single agent following multi-modality anthracycline based therapy

   2. Herceptin Hylecta is indicated in adults:
      i. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
      ii. As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

B. Compendial Uses
   HER2-positive breast cancer: may be substituted for intravenous trastuzumab and used as a single agent or in combination with other systemic therapies

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: Human epidermal growth factor receptor 2 (HER2) status.

III. CRITERIA FOR INITIAL APPROVAL

Breast Cancer

A. Authorization of up to 12 months may be granted for treatment of adjuvant treatment of HER2-positive breast cancer.
B. Authorization of 12 months may be granted for treatment of HER2-positive breast cancer with no response to preoperative systemic therapy, recurrent, unresectable, advanced, or metastatic (including brain metastases) disease.

C. Authorization of up to 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

A. Breast Cancer in the Adjuvant and Neoadjuvant Setting

Authorization of 12 months (up to 12 months total) may be granted for adjuvant or neoadjuvant treatment of breast cancer when all of the following criteria are met:

1. The member is currently receiving therapy with the requested medication
2. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen AND
    ii. No evidence of disease progression while on the current regimen

B. Breast Cancer with No Response to Preoperative Therapy or in the Recurrent, Unresectable, Advanced, or Metastatic Setting

Authorization of 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with the requested medication
2. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen AND
    ii. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Herceptin Hylecta.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Breast cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Herceptin Hylecta are covered in addition to using Herceptin Hylecta as a substitute for intravenous trastuzumab for HER2-positive breast cancer.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Herceptin Hylecta as a substitute for intravenous trastuzumab to treat HER2-positive breast cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen). Herceptin Hylecta may be used as a

single agent or in combination with other systemic therapies. Do not substitute for or with ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu).

VII. REFERENCES

1. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 7, 2022.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 7, 2022.