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:
      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

   2. Herceptin Hylecta is indicated in adults:
      a. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
      b. 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
   1. 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 grated for treatment of HER2-positive recurrent, unresectable advanced, or metastatic breast cancer.

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. Adjuvant and Neoadjuvant treatment of breast cancer

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 Herceptin Hylecta
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. Recurrent, Unresectable, Advanced, or Metastatic breast cancer

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

1. The member is currently receiving therapy with Herceptin Hylecta
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. REFERENCES

1. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 17, 2021.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 6.2020. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 17, 2021.