Reference number(s)
3017-A

SPECIALTY GUIDELINE 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 therapy

   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
   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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR APPROVAL

Breast Cancer

A. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.
B. Authorization of 12 months may be granted 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

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication outlined in section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

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 December 4, 2020.
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 November 30, 2020.