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.

FDA-Approved Indications

A. 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:
   1. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   2. As part of a treatment regimen with docetaxel and carboplatin
   3. As a single agent following multi-modality anthracycline based therapy

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

Breast Cancer
Authorization of 12 months may be granted for the treatment of adjuvant early stage or metastatic HER2-overexpressing breast cancer.

III. REFERENCES

1. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.