Policy Title:	Herceptin Hylecta ((trastuzumab and hyaluronidase-oysk) (subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/20/2019, 1/29/20, 4/15/20		
Revision Date:	12/20/2019, 1/29/20, 4/15/20		

Purpose: To support safe, effective and appropriate use of Herceptin Hylecta (trastuzumab and hyaluronidase-oysk).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Baseline left ventricular ejection fraction (LVEF) within normal limits; AND
- Patient is 18 years or older; AND
- Patient's cancer is human epidermal growth factor receptor 2 (HER2)-overexpressing and has one of the following:
    - Immunohistochemistry (IHC) assay 3+; OR
    - In situ hybridization (ISH) assay average HER2 copy number ≥ 6.0 signals/cell; OR
    - Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0; AND
- Will not be used in combination with trastuzumab or ado-trastuzumab emtansine; AND
- Herceptin Hylecta will not be used with intravenous chemotherapy agents; AND
- For new start to therapy, patient must have documentation of failure or intolerable side effects to one of the preferred biosimilar products, Kanjinti or Trazimera; OR
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements;

Breast cancer

- Used as adjuvant therapy as a single agent following anthracycline-based therapy ; OR

- Used for metastatic disease as a single agent in patients who have received one or more prior treatments for metastatic disease

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria; AND
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy, etc.), pulmonary toxicity (i.e., pneumonitis), neutropenia, infusion-related reactions, etc.; AND
    - LVEF has not had an absolute decrease of ≥ 16% from pre-treatment baseline and is within the institutional normal limits; OR
    - LVEF has not had an absolute decrease of ≥ 10% from pre-treatment baseline and is below the institutional lower limits of normal; AND
- For the adjuvant treatment of breast cancer, the patient has not exceeded a maximum of 52 weeks of therapy

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = *10* mg)**
Breast Cancer	Administer 600 mg/10,000 units subcutaneously once every three weeks	60 billable units every 21 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk

References:

1. Herceptin Hylecta [package insert]. South San Francisco, CA; Genentech, Inc; February 2019. Accessed May 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) trastuzumab and hyaluronidase human. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2019