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

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 failure or intolerable side effects to a trastuzumab biosimilar product; 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