



Trastuzumab (Herceptin) and Trastuzumab hyaluronidase-oysk (Herceptin Hylecta) Coverage Criteria

Description:

Trastuzumab (Herceptin) is a humanized IgG1 kappa monoclonal antibody that selectively binds with high affinity to the extracellular domain of the HER2 oncogene. Trastuzumab-mediated antibody-dependent cellular cytotoxicity (ADCC) preferentially acts on cancer cells that overexpress HER2 compared with cancer cells that do not overexpress HER2. In cells treated with trastuzumab, the HER2 receptor is downregulated which arrests the cell cycle, thereby inhibiting the proliferation of human tumor cells that overexpress HER2.

Trastuzumab hyaluronidase-oysk (Herceptin HYLECTA) is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase; hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan, which is a polysaccharide found in the extracellular matrix of the subcutaneous tissue.

Policy:

The intent of this policy is to define clinical characteristics to identify patients who qualify for trastuzumab (Herceptin), trastuzumab hyaluronidase-oysk (Herceptin HYLECTA) and their respective biosimilars require a prior authorization and will be covered when the criteria have been met.

Trastuzumab (Herceptin) or trastuzumab hyaluronidase-oysk (Herceptin HYLECTA) will be covered through Amida Care's medical benefit only.

Prior Authorization Criteria:

Trastuzumab (Herceptin), trastuzumab biosimilar, and Trastuzumab hyaluronidase-oysk (Herceptin HYLECTA) may be considered medically necessary in patients with breast cancer when there is clinical documentation (including, but not limited to chart notes) confirming any one of the following diagnosis

- A. Invasive Breast Cancer that is HER2 over-expressing* if used as **ANY ONE** of the following:
 - i. Adjuvant therapy if **ANY ONE** of the following:

1. In combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.)
 2. As a single agent following anthracycline-based therapy
 - ii. Neoadjuvant therapy for breast preservation in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.)
 - iii. Treatment of recurrent or metastatic disease as **ANY ONE** of the following:
 1. Single agent in individuals who have received one or more prior treatments for metastatic disease
 2. First-line therapy in combination with paclitaxel
 3. In combination with endocrine therapy with hormone receptor-positive disease if individual is **ANY ONE** of the following:
 - a. Post-menopausal
 - b. Pre-menopausal and treated with ovarian ablation/suppression
 - c. Male receiving concomitant suppression of testicular steroidogenesis
 4. Disease is hormone receptor-negative OR hormone receptor-positive (with or without endocrine therapy) and used in combination with **ANY ONE** of the following:
 - a. Cytotoxic chemotherapy
 - b. Lapatinib
 - c. Pertuzumab and a taxane as first-line therapy
 - d. Pertuzumab as subsequent therapy with prior trastuzumab treatment in the absence of pertuzumab
- B. Gastric, Esophageal or Esophagogastric Junction cancers that are HER2-overexpressing* if **ALL** of the following:
- i. Disease is metastatic or locally advanced adenocarcinoma
 - ii. Used in combination therapy with cisplatin and fluorouracil (5FU) or capecitabine for first-line therapy
- C. Central Nervous System cancer if ALL of the following:
- i. Individual has leptomeningeal metastases from HER2-positive breast cancer
 - ii. Treatment will be administered intrathecally
- D. Gastric, Esophageal or Esophagogastric Junction cancers that are HER2-overexpressing* if ALL of the following:
- i. Disease is metastatic or locally advanced adenocarcinoma

- ii. Used in combination therapy with cisplatin and fluorouracil (5FU) or capecitabine for first-line therapy
- E. Uterine cancer if **ALL** of the following:
- i. Used in combination with carboplatin and paclitaxel
 - ii. Used for advanced (Stage III/IV) or recurrent uterine serous carcinoma

Administration and Authorization Period

- I. Trastuzumab is not considered to be a self-administered medication.
- II. Authorization may be reviewed annually. Clinical documentation (including, but not limited to chart notes) must be provided to confirm that current medical necessity criteria are met, and that the medication is providing clinical benefit, such as disease stability or improvement.

References:

1. Clinical Pharmacology online. Trastuzumab. Elsevier/Gold Standard. Accessed 9/2019.
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3. Prescribing information: Herceptin Hylecta™ for subcutaneous use. South San Francisco, CA: Genentech, Inc.; Revised 2/ 2019.
4. National Comprehensive Cancer Network® (NCCN) Drugs & Biologics Compendium ®: Trastuzumab. Accessed 11/2019.
5. National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology: Breast Cancer Version 1.2019. Accessed 9/2019.
6. National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers (Excluding the proximal 5cm of the stomach). Version 1.2019. Accessed 9/2019.
7. National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology: Gastric Cancer. Version 1.2019. Accessed 4/2019.
8. National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology: Uterine Neoplasms. Version 3.2019. Accessed 4/2019.
9. National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 1.2019. Accessed 4/2019.
10. Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual: Chapter 15. (CMS Publication No. 100-02). Retrieved from <http://www.cms.hhs.gov>.