SmartHealth

Ascension

Trastuzumab

(Herceptin®) J9355

Covered with prior authorization

Requests for trastuzumab (Herceptin®) may be approved when the following criteria is met:

- Diagnosis of breast cancer; **AND**
- HER2 (human epidermal growth factor receptor2) positive disease; **AND**
    - Dosing for **Metastatic** HER2-Overexpressing Breast Cancer is initial dose of 4 mg/kg as a 90 minute IV infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute IV infusions; **OR**
    - Dosing for **adjuvant treatment** of HER2-Overexpressing Breast Cancer is:
        - Initial dose of 4 mg/kg over 90 minute IV infusion followed by 2 mg/kg over 30 minute IV infusion weekly for 52 weeks; **OR**
        - Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30–90 minutes IV infusion every three weeks for 52 weeks.

OR

- Diagnosis of advanced, gastric cancer or gastroesophageal adenocarcinoma; **AND**
- HER2 (human epidermal growth factor receptor2) positive disease; **AND**
- Used with cisplatin in combination with either fluorouracil or capecitabine; **AND**
- Dosing is an initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks.

AND

- Individual has had a trial and intolerance to one preferred, biosimilar trastuzumab agent; **OR**
- Individual is currently stabilized on the trastuzumab (HERCEPTIN®).

AND

- Individual is ≥ 18 years of age.

AND

- Prescriber is an oncologist or hematologist.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Concurrent use of an anthracycline;

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
trastuzumab-dttb, biosimilar, Ontruzant [Q5112]	Trastuzumab (HERCEPTIN)
trastuzumab-pkrb, biosimilar, Herzuma [Q5113]	
trastuzumab-dkst, biosimilar, Ogivri [Q5114]	
trastuzumab-qyyp, biosimilar, Trazimera [Q5116]	
trastuzumab-anns, biosimilar, Kanjinti [Q5117]	

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Trastuzumab is a recombinant DNA-derived humanized monoclonal antibody that selectively binds the extracellular domain of the human epidermal growth factor receptor 2 (HER2) protein and inhibits the proliferation of human tumor cells that overexpress HER2. Herceptin® (trastuzumab) is a HER2/neu receptor antagonist indicated for:

- the treatment of HER2 overexpressing breast cancer
- the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma

References:

Bae, S. J., Kim, J. H., Ahn, S. G., Jeung, H.-C., & et al. (2021, June 4). Real-World Clinical Outcomes of Biosimilar Trastuzumab (CT-P6) in HER2-Positive Early-Stage and Metastatic Breast Cancer. *Frontiers in Oncology*, *11*(Article 689587). 10.3389/fonc.2021.689587

Early Breast Cancer Trialists' Collaborative group (EBCTCG). (2021, August 1). Trastuzumab for early-stage, HER2-positive breast cancer: a meta-analysis of 13864 women in seven randomised trials. *THE LANCET*, *11*(8), 11391150. https://doi.org/10.1016/S1470-2045(21)00288-6

HERCEPTIN® (trastuzumab) Label. (2010, October). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/103792s5250lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.