SmartHealth Ascension

Trastuzumab and hyaluronidase-oysk

(Herceptin Hylecta®) J9356

Covered with prior authorization

Requests for trastuzumab and hyaluronidase-oysk (Herceptin Hylecta®) may be approved when the following criteria is met:

- Diagnosis of breast cancer; **AND**
- HER2 (human epidermal growth factor receptor2) positive disease; **AND**
- trastuzumab and hyaluronidase-oysk is being used as **adjuvant treatment; AND**
    - In combination with paclitaxel or docetaxel following doxorubicin and cyclophosphamide; **OR**
    - In combination with docetaxel and carboplatin; **OR**
    - As monotherapy following multimodality anthracycline based therapy;

OR

- trastuzumab and hyaluronidase-oysk is used to treat **metastatic** disease; **AND**
    - In combination with paclitaxel as first line treatment; **OR**
    - Monotherapy following one or more combination chemotherapy treatments.

AND

- Dose is 600 mg/10,000 units (600 mg trastuzumab and 10,000 units hyaluronidase) administered subcutaneously over approximately 2-5 minutes once every three 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 or ado-trastuzumab emtansine (Kadcyla);

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

- Diagnosis of gastric or GEJ or esophageal carcinoma;
- 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 and hyaluronidase-oysk (Herceptin Hylecta)
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.

Herceptin Hylecta® is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, indicated in adults for:

- The treatment of HER2-overexpressing breast cancer.
- Select patients for therapy based on an FDA-approved companion diagnostic for trastuzumab.

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 Hylecta® *(trastuzumab and hyaluronidase-oysk) label*. (2019, February 28). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761106s000lbl.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.