Trastuzumab and hyaluronidase-oysk (Herceptin Hylecta™)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration Home Infusion Administration HCPCS: **J9356** per 10 mg *(of trastuzumab)*

Condition(s) listed in policy (*see criteria for details*)

- Breast cancer (HER2-positive)

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Trastuzumab is a recombinant DNA-derived humanized anti-*HER2* monoclonal antibody which is a mediator of antibody-dependent cellular cytotoxicity (ADCC). Hyaluronan is a polysaccharide that has been shown to increase the absorption rate of a trastuzumab product.

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for trastuzumab and hyaluronidase-oysk (Herceptin Hylecta™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast Cancer (HER2-Positive)

1. HER2-positive breast cancer, **AND**
2. Intolerable side effect with the preferred trastuzumab products, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera, that is not expected with Herceptin Hylecta, or contraindication to Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera

Covered Doses

Initial loading dose

Up to 600 mg/10,000 units (600 mg trastuzumab and 10,000 units hyaluronidase) given subcutaneously every three weeks

Coverage Period

Neoadjuvant/ Adjuvant therapy: Cover maximum of 1 year. No reauthorization.

Recurrent or Metastatic: Yearly

ICD-10:

C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, Z85.3

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for trastuzumab and hyaluronidase-oysk (Herceptin Hylecta™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

600 mg trastuzumab and 10,000 units hyaluronidase per 5 mL (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk) [Prescribing information]. South San Francisco, CA: Genentech, Inc.; 2/2019.
- National Comprehensive Cancer Network. Breast Cancer (Version 4.2023). Available at www.nccn.org.
- Wolff AC, Hammond MEH, Allison KH et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. J Clin Oncol. 2018; 36(20): 2105-2122.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee