

Specialty Guideline Management

Herceptin Hylecta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Herceptin Hylecta	trastuzumab and hyaluronidase-oysk

Indications

FDA-Approved Indications¹

Herceptin Hylecta is indicated for adjuvant treatment of adults with HER2-overexpressing node positive or node negative (estrogen receptor [ER]/progesterone receptor [PR] negative or with one high risk feature) breast cancer:

- as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- as part of a treatment regimen with docetaxel and carboplatin
- as a single agent following multi-modality anthracycline based therapy

Herceptin Hylecta is indicated in adults:

- in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
- as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

Compendial Uses²⁻³

HER2-positive breast cancer: may be substituted for intravenous trastuzumab and used as a single agent or in combination with other systemic therapies

Reference number(s)
3017-A

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status.

Coverage Criteria

Breast Cancer¹⁻³

Authorization of up to 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.

Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.

Authorization of 12 months may be granted for treatment of HER2-positive breast cancer with no response to preoperative systemic therapy, recurrent, advanced, unresectable, or metastatic (including brain metastases) disease.

Authorization of 12 months may be granted for treatment of HER2-negative metastatic breast cancer when used in combination with neratinib and fulvestrant or in combination with tucatinib with or without fulvestrant as third-line or later therapy.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

References

1. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed February 13, 2026.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 3, 2025.