

Generic Name: pertuzumab

Therapeutic Class or Brand Name: Perjeta

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 3/8/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of one of the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Breast Cancer

- i. Documentation of human epidermal growth factor receptor-2 (HER2)-positive disease and meets one of the following criteria (1, 2, or 3):
 1. Documentation of metastatic disease
 - a. Used in combination with trastuzumab and docetaxel
 - b. No prior anti-HER2 therapy or chemotherapy for metastatic disease
 2. Documentation of use for neoadjuvant treatment
 - a. Locally advanced, inflammatory, or early-stage disease (either greater than 2 cm in diameter or node positive)
 - b. Used in combination with trastuzumab and chemotherapy as part of a complete treatment regimen in one of the following combinations:
 - i. Used in combination with trastuzumab and docetaxel
 - ii. Used in combination with trastuzumab and docetaxel after three to four preoperative cycles of fluorouracil, epirubicin, and cyclophosphamide (FEC)
 - iii. Used in combination with trastuzumab, docetaxel, and carboplatin (TCH)
 - iv. Used in combination with paclitaxel and trastuzumab after four preoperative cycles of dose-dense doxorubicin and cyclophosphamide (ddAC)
 3. Documentation of use for adjuvant treatment
 - a. Documentation of early breast cancer at high risk of recurrence

- b. Used in one of the following regimens (i or ii)
 - i. Used in combination with trastuzumab
 - ii. Administered as part of a regimen including standard anthracycline (ie. doxorubicin) and/or taxane-based chemotherapy (ie. paclitaxel, docetaxel, nab-paclitaxel) with trastuzumab

Other Uses With Supportive Evidence

- C. Appendiceal cancer
 - D. Biliary tract cancer
 - E. Central nervous system cancer
 - F. Gallbladder cancer
 - G. Colon cancer
 - H. Rectal cancer
 - I. Salivary gland tumors
 - J. Small bowel adenocarcinoma
- II. Minimum age requirement: 18 years old and older
 - III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
 - IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
 - V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Maximum of 21-day supply (3-week cycle)
 - Loading dose: 840 mg x 1, then 420 mg every 3 weeks

- Re-administer loading dose of 840 mg if time between two sequential dose is greater than or equal to 6 weeks

APPROVAL LENGTH

- **Authorization:** Neoadjuvant: 6 cycles. Adjuvant: 18 cycles (1 year). Metastatic breast cancer: 1 year.
- **Re-Authorization:** One year for metastatic breast cancer. No renewals for neoadjuvant or adjuvant breast cancer. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 2.2026. Updated February 27, 2026. Accessed March 8, 2026. www.nccn.org/proessional/physician_gls/pdf/breast.pdf
2. Perjeta. Prescribing information. Genentech, Inc. 2025. Accessed March 8, 2026. www.gene.com/download/pdf/perjeta_prescribing.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.