

Reference number(s)
1899-A

# SPECIALTY GUIDELINE MANAGEMENT

## PERJETA (pertuzumab)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

1. Metastatic breast cancer  
In combination with trastuzumab and docetaxel for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
2. Neoadjuvant treatment of breast cancer  
In combination with trastuzumab and chemotherapy as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.
3. Adjuvant treatment of breast cancer  
In combination with trastuzumab and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.

##### B. Compendial Uses

Treatment of recurrent or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-positive breast cancer

All other indications are considered experimental/investigational and are not a covered benefit.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Breast cancer**

- A. Authorization of 6 months may be granted for neoadjuvant therapy of HER2-positive breast cancer.
- B. Authorization of 12 months may be granted for adjuvant therapy of HER2-positive breast cancer.
- C. Authorizations of 12 months may be granted for the treatment of recurrent or metastatic HER2-positive breast cancer.

#### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

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#### IV. REFERENCES

1. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; December 2018.
2. The NCCN Drugs & Biologics Compendium<sup>®</sup> © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 28, 2019.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 3.2018. [https://www.nccn.org/professionals/physician\\_gls/pdf/breast.pdf](https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf). Accessed January 26, 2019.