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| 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 Indications¹

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^{2,3}

Treatment of recurrent HER2-positive breast cancer

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

II. CRITERIA FOR INITIAL APPROVAL¹⁻³

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 2017.
2. The NCCN Drugs & Biologics Compendium™ © 2018 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 17, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2017. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf . Accessed January 17, 2018.