Reference number(s)
2472-A

STANDARD MEDICARE PART B 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 for the 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
1. Treatment of recurrent or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-positive breast cancer
2. HER2-amplified and RAS wild-type colorectal cancer in combination with trastuzumab

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer
1. Authorization of 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer
2. Authorization of 12 months may be granted for adjuvant treatment of HER2-positive breast cancer
3. Authorization of 12 months may be granted for the treatment of recurrent or metastatic HER2-positive breast cancer

B. Colorectal Cancer
Authorization of 12 months may be granted for the treatment of HER2-amplified colorectal cancer.

III. CONTINUATION OF THERAPY

Authorization may be granted for all members (including new members) who are continuing with Perjeta therapy when all of the criteria below are met. Authorization duration will be 6 months for neoadjuvant treatment of breast cancer and 12 months for other settings.

A. The member is currently receiving treatment with Perjeta.
B. Perjeta is being used to treat a diagnosis or condition enumerated in Section II.
C. Perjeta has been effective for treating the diagnosis or condition.

IV. REFERENCES

a. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; December 2018.
b. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 6, 2020.
c. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 3.2019. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 6, 2020.