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. Adjuvant treatment of locally advanced HER2-positive breast cancer
3. HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with trastuzumab
4. HER2-positive recurrent salivary gland tumors 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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: human epidermal growth factor receptor 2 (HER2) status, RAS mutation status (where applicable), BRAF mutation status (where applicable)

III. 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 treatment of recurrent or metastatic HER2-positive breast cancer.

B. Colorectal Cancer
Authorization of 12 months may be granted for treatment of HER2-amplified and RAS and BRAF wild-type colorectal cancer.

C. Salivary Gland Tumors
Authorization of 12 months may be granted for treatment of HER2-positive salivary gland tumors.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are continuing with Perjeta therapy when all of the following criteria are met. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

A. The member is currently receiving treatment with Perjeta
B. Perjeta is being used to treat a diagnosis or condition enumerated in Section III
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen AND
   2. No evidence of disease progression while on the current regimen

V. REFERENCES

1. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; January 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 10, 2020.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 6.2020. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 10, 2020.