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

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 (including appendiceal adenocarcinoma and anal adenocarcinoma) in combination with trastuzumab
4. HER2-positive recurrent salivary gland tumors
5. HER2-positive hepatobiliary cancers

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: 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 pre-operative (neoadjuvant) therapy of HER2-positive breast cancer in combination with trastuzumab and chemotherapy for locally advanced, inflammatory or early stage breast cancer (either greater than 2 cm in diameter or node positive).
2. Authorization of 12 months may be granted for adjuvant therapy of HER2-positive breast cancer that is either node-positive or at high risk for recurrence in combination with trastuzumab and chemotherapy.
3. Authorizations of 12 months may be granted for the treatment of recurrent or metastatic HER2-positive breast cancer or HER2-positive breast cancer with no response to preoperative systemic therapy in combination with trastuzumab.

B. **Colorectal Cancer**
Authorization of 12 months may be granted for treatment of colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, with HER2-amplified and RAS and BRAF wild-type disease not previously treated with HER2 inhibitor in combination with trastuzumab when either of the following are met:
1. Member is not appropriate for intensive therapy
2. Perjeta will be used as subsequent therapy for progression of advanced or metastatic disease

C. **Salivary Gland Tumor**
Authorization of 12 months may be granted for treatment of recurrent HER2-positive salivary gland tumors in combination with trastuzumab.

D. **Hepatobiliary Cancers**
Authorization of 12 months may be granted for subsequent treatment of unresectable or metastatic HER2-positive hepatobiliary cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer) when used in combination with trastuzumab.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

V. REFERENCES

1. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 9, 2022.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 9, 2022.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 2.2022. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf Accessed December 9, 2022.