Draft Revised Policy: Do Not Implement

Pertuzumab (Perjeta®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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.

FDA-Approved Indications

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.

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.

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.

Compendial Uses

- HER2-positive breast cancer
- HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma and anal adenocarcinoma)
- HER2-positive salivary gland tumors
- HER2-positive biliary tract cancers

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

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)

COVERAGE CRITERIA

Breast Cancer

- Authorization of 12 months may be granted for pre-operative (neoadjuvant) treatment 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).
- Authorization of 12 months may be granted for adjuvant treatment of HER2-positive breast cancer in combination with trastuzumab with or without chemotherapy.
- 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 with or without chemotherapy.

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 in combination with trastuzumab when either of the following are met:

- Member is not appropriate for intensive therapy
- The requested medication will be used as subsequent therapy for progression of advanced or metastatic disease and has disease not previously treated with HER2 inhibitor.

Salivary Gland Tumor

Authorization of 12 months may be granted for treatment of recurrent, unresectable or metastatic HER2-positive salivary gland tumors in combination with trastuzumab.

Biliary Tract Cancers

Authorization of 12 months may be granted for subsequent treatment of unresectable, resected gross residual (R2) disease, or metastatic HER2-positive biliary tract cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer) when used in combination with trastuzumab.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section 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.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Perjeta (Pertuzumab)	Breast Cancer	Route of Administration: Intravenous Initial: 840mg once Maintenance: 420mg every 3 weeks
Perjeta (Pertuzumab)	Colorectal Cancer, including ~~or~~ Appendiceal Adenocarcinoma and Anal Adenocarcinoma	Route of Administration: Intravenous Initial: 840mg once Maintenance: 420mg every 3 weeks
Perjeta (Pertuzumab)	Biliary Tract ~~Hepatobiliary~~ Cancer	Route of Administration: Intravenous Initial: 840mg once Maintenance: 420mg every 3 weeks

Perjeta (Pertuzumab)	Salivary Gland Tumors	Route of Administration: Intravenous Initial: 840mg once Maintenance: 420mg every 3 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 29, 2024.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 6.2024. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 29, 2024.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf Accessed November 29, 2024.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf Accessed November 29, 2024.

EFFECTIVE DATE

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