 Draft Revision Policy: Do Not Implement

Pertuzumab (Perjeta®); Pertuzumab-dpzb (Poherdy®)

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.

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 adults 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 adults 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 adults with HER2-positive early breast cancer at high risk of recurrence.

Compendial Uses

- Breast Cancer
- Colorectal Cancer
- Salivary Gland Tumors
- Biliary Tract Cancers
  - Gallbladder cancer
  - Intrahepatic cholangiocarcinoma
  - Extrahepatic cholangiocarcinoma
- Appendiceal Neoplasms and Cancers
  - Appendiceal adenocarcinoma
  - Goblet cell adenocarcinoma
  - Undifferentiated carcinoma not otherwise specified
- Small Bowel Adenocarcinoma

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, where applicable:

- HER2 status
- Hormone receptor (HR) status
- RAS mutation status
- BRAF mutation status

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.
- Authorization of 12 months may be granted for adjuvant treatment of HER2-positive breast cancer in combination with trastuzumab with or without chemotherapy for locally advanced or early stage disease.
- Authorizations of 12 months may be granted for treatment of recurrent unresectable 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.
- Authorization of 12 months may be granted for treatment of unresectable or metastatic HER2-positive breast cancer, as first-line therapy in combination with fam-trastuzumab deruxtecan-nxki (Enhertu).
- Authorization of 12 months may be granted for treatment of recurrent unresectable or metastatic HR-positive, HER2-positive breast cancer or disease with no response to preoperative systemic therapy, as first-line therapy in combination with an aromatase inhibitor, palbociclib (Ibrance), and trastuzumab.

Colorectal Cancer

Authorization of 12 months may be granted for treatment of colorectal cancer, including anal adenocarcinoma, with HER2-amplified and RAS and BRAF wild-type disease in combination with trastuzumab when any of the following are met:

- The requested medication will be used as initial treatment for unresectable metachronous metastases.
- 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 Tumors

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 gallbladder cancer and intrahepatic and extrahepatic cholangiocarcinoma) when used in combination with trastuzumab.

Appendiceal Neoplasms and Cancers

Authorization of 12 months may be granted for subsequent treatment of appendiceal neoplasms and cancers (including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified) when all of the following criteria are met:

- The disease is HER2-positive and RAS and BRAF wild-type
- The requested medication will be used in combination with trastuzumab
- The member has not received previous treatment with HER2 inhibitor

Small Bowel Adenocarcinoma

Authorization of 12 months may be granted for subsequent treatment of advanced or metastatic small bowel adenocarcinoma, with HER2-amplified and RAS and BRAF wild-type disease 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)	Biliary Tract Cancer	Route of Administration: Intravenous Initial: 840mg once Maintenance: 420mg every 3 weeks
Perjeta (Pertuzumab)	Breast Cancer	Route of Administration: Intravenous 420mg every 3 weeks Initial: 840mg once Maintenance: 420mg every 3 weeks
Perjeta (Pertuzumab)	Colorectal Cancer, including Appendiceal ~~Adenocarcinoma~~ Neoplasms and Cancers and Anal Adenocarcinoma	Route of Administration: Intravenous Initial: 840mg once Maintenance: 420mg every 3 weeks
~~Perjeta (Pertuzumab)~~	~~Biliary Tract 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
Perjeta (Pertuzumab)	Small Bowel Adenocarcinoma	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.; June 2025.
2. Poherdy [package insert]. Jersey City, NJ: Organon LLC; November 2025.
3. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 26, 2026.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed December 4, 2025.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed December 4, 2025.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Appendiceal Neoplasms and Cancers. Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/appendiceal.pdf. Accessed December 5, 2025.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed December 5, 2025.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer. Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed December 5, 2025.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancer. Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed December 10, 2025.

EFFECTIVE DATE

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