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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

**P&T Date: 12/04/2025**

**Pertuzumab Products**  
**Perjeta®** (pertuzumab)  
**Poherd®** (pertuzumab-dpzb)

**HCPCS:** Perjeta: J9306; Poherd: J3590

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

- A. Coverage of the requested drug is provided when all the following are met:
  - a. As first line treatment of recurrent or metastatic HER2+ disease in combination with trastuzumab and either docetaxel or paclitaxel (trastuzumab and pertuzumab may be continued if either docetaxel or paclitaxel is discontinued [for example, due to toxicity]) OR in subsequent therapy in combination with trastuzumab with or without cytotoxic therapy when not received in the first line setting
  - b. For neoadjuvant therapy in HER2+ breast cancer that is either node positive, the tumor size is greater than 2 cm in diameter, or locally advanced disease when used in combination with trastuzumab and either paclitaxel or docetaxel following doxorubicin and cyclophosphamide, OR in combination with docetaxel and carboplatin.
  - c. For adjuvant therapy in node positive or hormone receptor negative breast cancer when used in combination with trastuzumab and either paclitaxel or docetaxel following doxorubicin and cyclophosphamide, OR in combination with docetaxel and carboplatin.
  - d. Should not be used if previous treatment failure has occurred with Perjeta
  - e. Detection of HER2 protein overexpression defined as in situ hybridization (ISH) positive by any of the following:
    - i. Single probe average HER2 copy number greater than or equal to 6.0 signals/cell  
OR
    - ii. Dual-probe HER2/CEP17 ratio greater than or equal to 2.0  
OR
    - iii. Dual-probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell
- B. Quantity Limitations, Authorization Period and Renewal Criteria
  - a. Quantity Limits: Align with FDA recommended dosing
  - b. Authorization Period: Aligns with FDA recommended dosing or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
  - c. Renewal Criteria:

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- i. Metastatic breast cancer and adjuvant therapy: Treatment may be continued until unacceptable toxicity or disease progression
- ii. Neoadjuvant therapy: Not applicable as no further authorization will be provided

\*\*\*Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

### **Background Information:**

- Perjeta and the biosimilar are a HER2/neu receptor antagonists indicated for:
  - Use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
  - Use 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 patients with HER2-positive early breast cancer at high risk of recurrence.
- Per the 2025 National Comprehensive Cancer Network (NCCN) guidelines for breast cancer, patients are eligible for adjuvant HER2-directed treatment if they have HER2-positive breast cancer defined as:
  - Single probe average HER2 copy number greater than or equal to 6.0 signals/cell, OR
  - Dual probe HER2/CEP17 ratio greater than or equal to 2.0, OR
  - Dual probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell
- When used for adjuvant or neoadjuvant therapy, NCCN guidelines recommend use of Perjeta in combination with trastuzumab and either paclitaxel or docetaxel following doxorubicin and cyclophosphamide or in combination with docetaxel and carboplatin. Neoadjuvant therapy is given for up to 6 months and adjuvant therapy is given for up to 1 year.
- When used in metastatic disease, Perjeta should be given first-line in combination with trastuzumab and either docetaxel or paclitaxel per the NCCN guidelines. Perjeta can be used in subsequent lines of therapy in combination with trastuzumab with or without cytotoxic therapy. Treatment with Perjeta is recommended to continue indefinitely until disease progression or unacceptable toxicity.
- NCCN treatment guidelines also do not recommend use of Perjeta following a previous failure.

## References:

1. Perjeta [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2025.
2. Poherdy [prescribing information]. Jersey City, NJ: Shanghai Henlius Biologics Co., Ltd.; November 2025.
3. National Comprehensive Cancer Network. Breast cancer (Version 5.2025). 2025 Oct 16. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/breast.pdf](https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf). Accessed on November 14, 2025.
4. Baselga J, Gelmon KA, Verma S, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. NEJM. 2012; 366: 109 - 19.
5. Awada A, Bozovic-Spasojevic I, & Chowet L. New therapies in HER2-positive breast cancer: a major step towards a cure of the disease? Cancer Treat Rev. 2012 Aug; 38 (5): 494 - 504.
6. Perez EA & Spano JP. Current and emerging targeted therapies for metastatic breast cancer. Cancer. 2012 Jun 15; 118 (12): 3014 - 25.
7. Gianni L, Pienkowski T, Im YH, et al. Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2 positive breast cancer (NeoSphere): a randomized multicentre, open-label, phase 2 trial. Lancet Oncol. 2012; 13: 25 - 32.
8. Schneeweiss A, Chia S, Hickish T, et al. Pertuzumab plus trastuzumab in combination with standard neoadjuvant anthracycline-containing and anthracycline-free chemotherapy regimens in patients with HER2-positive early breast cancer: a randomized phase II cardiac safety study (TRYPHAENA). Ann Onc. 2013; 24: 2278 - 84.
9. Von Minckwitz G, Procter M, de Azambuja E, et al. Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer (APHINITY). NEJM. 2017; 377: 122 – 31.

| Policy History   |                                                   |                                                                                                                                                                                                                                                                                                 |                  |                                                   |      |     |     |     |       |     |      |     |
|------------------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------|------|-----|-----|-----|-------|-----|------|-----|
| #                | Date                                              | Change Description                                                                                                                                                                                                                                                                              |                  |                                                   |      |     |     |     |       |     |      |     |
| 2.6              | Effective Date: 12/04/2025                        | Updated to add Poherdy. The title of the policy was changed from Perjeta to the Pertuzumab Products Policy                                                                                                                                                                                      |                  |                                                   |      |     |     |     |       |     |      |     |
| 2.5              | Effective Date: 04/10/2025                        | Annual review of criteria was performed, no changes were made                                                                                                                                                                                                                                   |                  |                                                   |      |     |     |     |       |     |      |     |
| 2.4              | Effective Date: 04/11/2024                        | Annual review of criteria was performed, no changes were made                                                                                                                                                                                                                                   |                  |                                                   |      |     |     |     |       |     |      |     |
| 2.3              | Effective Date: 04/06/2023                        | Updated approval length to allow for no less than a 60 day approval duration                                                                                                                                                                                                                    |                  |                                                   |      |     |     |     |       |     |      |     |
| 2.2              | Effective Date: 04/14/2022                        | Updated authorization period to align with FDA dosing or NCCN guidelines for up to 6 months of therapy                                                                                                                                                                                          |                  |                                                   |      |     |     |     |       |     |      |     |
| 2.1              | Effective Date: 04/08/2021                        | Annual review of criteria was performed, no changes were made                                                                                                                                                                                                                                   |                  |                                                   |      |     |     |     |       |     |      |     |
| 2.0              | Effective Date: 12/01/2020                        | UM medical management system update for PPO <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table> | Line of Business | PA Required in Medical Management System (Yes/No) | BCBS | Yes | BCN | Yes | MAPPO | Yes | BCNA | Yes |
| Line of Business | PA Required in Medical Management System (Yes/No) |                                                                                                                                                                                                                                                                                                 |                  |                                                   |      |     |     |     |       |     |      |     |
| BCBS             | Yes                                               |                                                                                                                                                                                                                                                                                                 |                  |                                                   |      |     |     |     |       |     |      |     |
| BCN              | Yes                                               |                                                                                                                                                                                                                                                                                                 |                  |                                                   |      |     |     |     |       |     |      |     |
| MAPPO            | Yes                                               |                                                                                                                                                                                                                                                                                                 |                  |                                                   |      |     |     |     |       |     |      |     |
| BCNA             | Yes                                               |                                                                                                                                                                                                                                                                                                 |                  |                                                   |      |     |     |     |       |     |      |     |
| 1.9              | Effective Date: 04/16/2020                        | Annual review of criteria was performed, no changes were made                                                                                                                                                                                                                                   |                  |                                                   |      |     |     |     |       |     |      |     |

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|     |                               |                                                                                             |                                                   |
|-----|-------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| 1.8 | Effective Date:<br>01/01/2020 | UM medical management system update for BCNA and MAPPO                                      |                                                   |
|     |                               | Line of Business                                                                            | PA Required in Medical Management System (Yes/No) |
|     |                               | BCBS                                                                                        | No                                                |
|     |                               | BCN                                                                                         | Yes                                               |
|     |                               | MAPPO                                                                                       | Yes                                               |
|     |                               | BCNA                                                                                        | Yes                                               |
| 1.7 | Effective Date:<br>05/09/2019 | Updated criteria per oncology vendor                                                        |                                                   |
| 1.6 | Effective Date:<br>11/01/2018 | Updated criteria per oncology vendor                                                        |                                                   |
| 1.5 | Effective Date:<br>08/09/2018 | Criteria update to include new indication for adjuvant therapy in early stage breast cancer |                                                   |
| 1.4 | Effective Date:<br>11/09/2017 | Annual review of criteria was performed, no changes were made                               |                                                   |
| 1.3 | Effective Date:<br>11/10/2016 | Annual review of criteria was performed, no changes were made                               |                                                   |
| 1.2 | Effective Date:<br>04/01/2015 | UM medical management system update for BCN                                                 |                                                   |
|     |                               | Line of Business                                                                            | PA Required in Medical Management System (Yes/No) |
|     |                               | BCBS                                                                                        | No                                                |
|     |                               | BCN                                                                                         | Yes                                               |
|     |                               | MAPPO                                                                                       | No                                                |
|     |                               | BCNA                                                                                        | No                                                |
| 1.1 | Effective Date:<br>02/13/2014 | Criteria update                                                                             |                                                   |
| 1.0 | Effective Date:<br>07/10/2012 | New Policy                                                                                  |                                                   |
|     |                               | Line of Business                                                                            | PA Required in Medical Management System (Yes/No) |
|     |                               | BCBS                                                                                        | No                                                |
|     |                               | BCN                                                                                         | No                                                |
|     |                               | MAPPO                                                                                       | No                                                |
|     |                               | BCNA                                                                                        | No                                                |

\* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.