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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: 04/16/2026

Phesgo™ (pertuzumab, trastuzumab and hyaluronidase–zzxf)

HCPCS: J9316

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. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by or in consultation with an oncologist
 - d. Must have human epidermal growth factor receptor 2 (HER2) positive breast cancer 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
 - e. Must be used with concomitant treatment according to FDA indication or NCCN category 1 or 2A recommendation
 - f. Should not be used if previous treatment failure has occurred with Perjeta®
 - g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria:
 - i. When used as neoadjuvant breast cancer treatment: No renewal allowed
 - ii. When used as adjuvant breast cancer treatment: Treatment continued until unacceptable toxicity or disease progression for up to a total of 52 weeks of therapy
 - iii. For metastatic breast cancer: Treatment continued until unacceptable toxicity or disease progression

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***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:

- Herceptin®, Herceptin Hylecta™, trastuzumab biosimilars, and Perjeta are anti-HER2 monoclonal antibodies that bind to the HER2 receptor and inhibit proliferation of tumor cells that overexpress the receptor. Breast cancer is one tumor type that can be positive for the HER2 receptor. Herceptin, Herceptin Hylecta, trastuzumab biosimilars, and Perjeta have been studied in HER2 breast cancer and are guideline recommended for use.
- Phesgo is a combination product which includes the same active ingredients as Perjeta and Herceptin along with hyaluronidase. The hyaluronidase component increased permeability of the subcutaneous tissue which increases the absorption rate of the active ingredients when given simultaneously. It has been approved for the same breast cancer indications as Herceptin, Herceptin Hylecta, trastuzumab biosimilars, and Perjeta. The indications include use in combination with 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); in combination with chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence; and in combination with 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. When used as neoadjuvant therapy, Phesgo should be given every 3 weeks preoperatively for 3 to 6 cycles. When used as adjuvant therapy, Phesgo should be given for a total of 52 weeks of therapy. When used in metastatic disease, treatment should continue indefinitely until unacceptable toxicity or disease progression.
- The National Comprehensive Cancer Network (NCCN) 2026 Breast Cancer guidelines support the use of the American Society of Clinical Oncology (ASCO)/College of American Pathologist (CAP) HER2 testing guidelines. The guidelines define tumors as HER2-positive when they meet any of the following: a single probe average HER2 copy number greater than or equal to 6.0 signals/cell, a dual-probe HER2/CEP17 ratio greater than or equal to 2.0, or a dual-probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell.
- NCCN guidelines category 1 recommendations are based on high levels of evidence and uniform consensus that the recommendation is appropriate. Category 2A recommendations are based on a lower level of evidence but still have NCCN uniform consensus the recommendations are appropriate. Category 2B and lower recommendations are based on low levels of evidence and do not have consensus the recommendation is appropriate, therefore, these treatment regimens should only be used when all other options have been exhausted.
- Where guidelines recommend use in combination with other agents as part of a treatment regimen it should be administered as such. Studies have been completed to support use as combination therapy in these scenarios. There may be situations where Phesgo use as a single agent is warranted, for example, as a replacement for combination therapy of Perjeta and Herceptin. When recommended, Phesgo can be given as monotherapy.
- Treatment guidelines do not recommend use of pertuzumab following a previous treatment failure. Due to Phesgo having pertuzumab as an active ingredient, it should not be used in situations where patients have failed a prior regimen containing pertuzumab.

References:

1. Phesgo [prescribing information]. South San Francisco, CA: Genentech, Inc.; November 2024.
2. Perjeta [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2025.
3. Herceptin [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2024.
4. Clinicaltrials.gov. A phase III, randomized, multicenter, open-label, two-arm study to evaluate the pharmacokinetics, efficacy, and safety of subcutaneous administration of the fixed-dose combination of pertuzumab and trastuzumab in combination with chemotherapy in patients with HER2-positive early breast cancer (NCT03493854). Available at: <https://clinicaltrials.gov/ct2/show/NCT03493854?term=NCT03493854&draw=2&rank=1>. Accessed on June 29, 2020.
5. Clinicaltrials.gov. A randomized, multicenter, open-label cross-over study to evaluate patient preference and satisfaction of subcutaneous administration of the fixed-dose combination of pertuzumab and trastuzumab in patients with HER2-positive early breast cancer (NCT03674112). Available at: <https://clinicaltrials.gov/ct2/show/NCT03674112?term=NCT03674112&draw=2&rank=1>. Accessed on June 29, 2020.
6. American Cancer Society. How common is breast cancer. 2020 Jan 8. Available at: <https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html>. Accessed on June 29, 2020.
7. National Comprehensive Cancer Network. Breast cancer (Version 1.2026). 2026 Jan 16. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed on February 24, 2026.

Policy History												
#	Date	Change Description										
1.8	Effective Date: 04/16/2026	Annual review – no changes to the criteria at this time										
1.7	Effective Date: 04/10/2025	Annual review – no changes to the criteria at this time										
1.6	Effective Date: 04/11/2024	Annual review – no changes to the criteria at this time										
1.5	Effective Date: 04/06/2023	Updated approval length to allow for at least a 60 day approval duration										
1.4	Effective Date: 08/04/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time										
1.3	Effective Date: 08/12/2021	Annual review – no changes to the criteria at this time										
1.2	Effective Date: 12/01/2020	UM medical management system update for BCBS <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
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1.1	Effective Date: 09/25/2020	UM medical management system update for BCN, MAPPO, and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</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	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.0	Effective Date: 08/13/2020	New policy										
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>			Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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** 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>.*