Reference number(s)
4704-A

Standard Medicare Part B Management Phesgo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Phesgo	pertuzumab, trastuzumab, and hyaluronidase-zzxf

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[1]

Phesgo is indicated for use in combination with chemotherapy for the neoadjuvant treatment of adult 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.

Phesgo is indicated for use in combination with chemotherapy for the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence.

Phesgo is indicated for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Compendial Uses[2,3]

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HER2-positive breast cancer: May be substituted anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this document should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions: Human epidermal growth factor receptor 2 (HER2) status.

Coverage Criteria

Breast Cancer[1-3]

- Authorization of 12 months may be granted for pre-operative (neoadjuvant) treatment of HER2-positive breast cancer in combination with 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.
- Authorization of 12 months may be granted for treatment of HER2-positive recurrent unresectable or metastatic breast cancer or HER2-positive breast cancer with no response to preoperative systemic therapy.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Adjuvant and neoadjuvant treatment of breast cancer

Authorization of 12 months (up to 12 months total) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with requested medication
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Breast Cancer with no response to preoperative therapy or in the recurrent unresectable, or metastatic setting

Authorization of 12 months may be granted when all of the following criteria are met:

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- The member is currently receiving therapy with requested medication
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this document were created after examining the following resources:

- The prescribing information for Phesgo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Breast cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Phesgo are covered in addition to HER2-positive breast cancer where Phesgo is substituted anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Phesgo to treat recurrent unresectable HER2-positive breast cancer in addition to the compendial indications in the summary of evidence section can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Phesgo [package insert]. South San Francisco, CA: Genentech, Inc.; November 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 8, 2025.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. December 8, 2025.

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