Reference number(s)
4704-A

STANDARD MEDICARE PART B MANAGEMENT

PHESGO (pertuzumab, trastuzumab, and hyaluronidase-zzxf)

POLICY

I. 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.

A. 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

2. 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.

3. 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.

B. Compendial Uses

Treatment of recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer

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

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

Breast Cancer

A. Authorization of up to 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 (either greater than 2 cm in diameter or node positive).

B. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer that is either node-positive or at high risk for recurrence in combination with chemotherapy.
C. Authorization of 12 months may be granted for the treatment of HER2-positive recurrent or metastatic breast cancer or HER2-positive breast cancer with no response to preoperative systemic therapy.

IV. CONTINUATION OF THERAPY

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

A. **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:
1. The member is currently receiving therapy with requested medication
2. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen AND
    ii. No evidence of disease progression while on the current regimen

B. Breast Cancer with no response to preoperative therapy or in the recurrent, unresectable, advanced or metastatic setting
Authorization of 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with requested medication
2. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen AND
    ii. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Phesgo.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. 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 recurrent HER2-positive breast cancer.

VI. EXPLANATION OF RATIONALE

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

Support for using Phesgo to treat recurrent HER2-positive breast cancer 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).

VII. REFERENCES

1. Phesgo [package insert]. South San Francisco, CA: Genentech, Inc; June 2020.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 9, 2022.
3. Von Minckwitz, G. *et al*. Adjuvant Pertuzumab and Trastuzumab in Early HER2-Positive Breast Cancer. *N. Engl. J. Med.* 377, 122–131 (2017). Available at: https://www.nejm.org/doi/full/10.1056/nejmoa1703643