Reference number(s)
3986-A

SPECIALTY GUIDELINE 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. Neoadjuvant treatment of breast cancer
   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. Adjuvant treatment of breast cancer
   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. Metastatic breast cancer (MBC)
   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
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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status

III. CRITERIA FOR INITIAL APPROVAL

Breast Cancer

1. 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 (either greater than 2 cm in diameter or node positive).
2. Authorization of 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.
3. Authorization of 12 months may be granted for the treatment of HER2-positive recurrent or metastatic breast cancer.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III 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.

V. REFERENCES

1. Phesgo [package insert]. South San Francisco, CA: Genentech, Inc; June 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 27, 2020.
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