Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications
Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)

APPROVAL CRITERIA

Requests for Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) may be approved if the following criteria are met:

I. Individual has a diagnosis of HER2-positive (HER2+) breast cancer (NCCN 1) confirmed by *one* of the following:
   A. Immunohistochemistry (IHC) is 3 +;
      OR
   B. In situ hybridization (ISH) positive;

AND

C. **One of the following:**
   1. Individual is using as neoadjuvant treatment; **AND**
   2. Individual is using in combination with chemotherapy; **AND**
   3. Individual has a diagnosis of 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;

   OR
   4. Individual is using as adjuvant treatment; **AND**
   5. Individual is using in combination with chemotherapy; **AND**
   6. Individual has a diagnosis of early breast cancer at high risk of recurrence;

   OR
   7. Individual is using for the treatment of metastatic breast cancer; **AND**
   8. Individual has not received prior anti-HER2 therapy or chemotherapy for metastatic disease; **AND**
   9. Individual is using in one of the following ways:
      a. Phesgo in combination with docetaxel; **OR**
      b. Phesgo alone after discontinuing combination therapy with docetaxel and continues with Phesgo until disease progression (Swain 2015);

OR

II. Individual is using Phesgo as a substitute anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy (NCCN 2A).

Requests for Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) may not be approved for the following:

I. For all other indications not listed above.

Note:
Phesgo has black box warnings for cardiomyopathy, embryo-fetal toxicity, and pulmonary toxicity. Phesgo administration can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF, with greatest risk when administered concurrently with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue Phesgo for cardiomyopathy. Exposure to Phesgo can result in embryo-fetal death and birth defects. Discontinue Phesgo for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 30, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 30, 2021.
    a. Breast Cancer. V4.2021. Revised April 28, 2021.
6. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) injection for subcutaneous use. [Package Insert]. South San Francisco, CA. Genentech; June, 2020.
7. Swain SM, Baselga J, Kim SB, et al. Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. N Engl J Med. 2015;372(8):724-734. doi:10.1056/NEJMoa1413513 Available at: https://www.nejm.org/doi/pdf/10.1056/NEJMoa1413513?articleTools=true. Accessed July 13, 2021.