

Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)

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

Medications	Quantity Limit
Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)	May be subject to quantity limit

APPROVAL CRITERIA

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

- I. Individual is under 19 years of age;

OR

- II. Individual has a diagnosis of HER2-positive (HER2+) breast cancer 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

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

Requests for Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. 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>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 21, 2024.
 - a. Breast Cancer. V2.2024. Revised March 11, 2024.
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>.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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