Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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

II. **One of the following:**
   A. Individual is using as neoadjuvant treatment; **AND**
   B. Individual is using in combination with chemotherapy; **AND**
   C. 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
   D. Individual is using as adjuvant treatment; **AND**
   E. Individual has a diagnosis of early breast cancer at high risk of recurrence;

   OR
   F. Individual has a diagnosis of metastatic breast cancer; **AND**
   G. Individual has not received prior anti-HER2 therapy or chemotherapy for metastatic disease; **AND**
   H. Individual is using Phesgo in combination with docetaxel.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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

I. For all other indications not listed above; **OR**
II. If used as a substitute for or with pertuzumab, trastuzumab, ado-trastuzumab emtansine (Kadcyla), or fam-trastuzumab deruxtecan (Enhertu) as a single agent.

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.: 2020. 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: July 20, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 20, 2020.
    a. Breast Cancer. V5.2020. Revised July 15, 2020.
6. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) injection for subcutaneous use. [Package Insert]. South San Francisco, CA. Genentech; June, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.