SmartHealth

Ascension

Pertuzumab/trastuzumab/ hyaluronidase-zzxf

(Phesgo®) J9316

Covered with prior authorization

Pertuzumab/trastuzumab/hyaluronidase-zzxf (Phesco®) may be authorized when the following criteria are met:

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

AND

- Individual is using Phesgo in combination with chemotherapy; **AND**
- Individual has not received prior anti-HER2 therapy or chemotherapy for metastatic disease; **AND**
- Individual is using in one of the following ways:
    - Phesgo® in combination with docetaxel; **OR**
    - Phesgo® alone after discontinuing combination therapy with docetaxel and continues with Phesgo® until disease progression; **AND**
- Dosing is:
    - Initial dose of 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase
    - Followed every 3 weeks by a dose of 600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase.

OR

- Individual is using as neoadjuvant treatment; **AND**
- Dosing is:
    - Initial dose of 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase
    - Followed every 3 weeks by a dose of 600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase preoperatively for 3 to 6 cycles.

OR

- Individual is using as adjuvant treatment; **AND**
- Dosing is:
    - Initial dose of 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

    - Followed every 3 weeks by a dose of 600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase postoperatively for a total of 1 year (up to 18 cycles).

OR

- Individual is using Phesgo® as a substitute anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy; **AND**
- Dosing is
    - Initial dose of 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase
    - Followed every 3 weeks by a dose of 600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Phesgo® is a combination of pertuzumab and trastuzumab, HER2/neu receptor antagonists, and hyaluronidase, an endoglycosidase, indicated for:

- Use in combination with chemotherapy as:
    - neoadjuvant treatment of 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.
    - adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence
- Use in combination with docetaxel for treatment of patients with HER2 positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

References:

National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved April 25, 2022, from https://www.nccn.org/guidelines/category_1
Phesgo® (pertuzumab, trastuzumab, and hyaluronidase-zzxf) Label. (2020, June). Accessdata.fda.gov. Retrieved April 25, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761170s000lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.