PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Phesgo Prior Authorization Policy
- Phesgo® (pertuzumab, trastuzumab, and hyaluronidase-zzxf subcutaneous injection – Genentech)

REVIEW DATE: 08/07/2024

OVERVIEW

Phesgo, a combination of pertuzumab, trastuzumab, and hyaluronidase-zzxf, is indicated for the following uses:[1]

- **Early breast cancer**, for use in combination with chemotherapy for the neoadjuvant treatment of adults with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer (either > 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. It is also indicated for the adjuvant treatment of adults with HER2-positive early breast cancer at high risk of recurrence.
- **Metastatic breast cancer**, for use in combination with docetaxel for the treatment of adults with HER2-positive disease who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Patients should be selected for therapy based on an FDA-approved companion diagnostic test.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for **breast cancer** (version 4.2024 – July 3, 2024) note that Phesgo may be substituted anywhere that the combination of Perjeta® (pertuzumab intravenous [IV] infusion) and trastuzumab IV are given as part of systemic therapy.[2] The guidelines note that Phesgo has different dosing and administration instructions compared with the IV products. For preoperative (neoadjuvant)/adjuvant therapy in HER2-positive disease, docetaxel + carboplatin + trastuzumab + Perjeta is a preferred regimen (category 2A). There are also other chemotherapy regimens listed that are used with trastuzumab + Perjeta. In the neoadjuvant/adjuvant setting, HER-2 targeted therapy is given for up to 1 year. In the recurrent unresectable (local or regional) or metastatic setting, the "Preferred Regimens" are Perjeta + trastuzumab + docetaxel (category 1) or Perjeta + trastuzumab + paclitaxel (category 2A). In this setting, chemotherapy + trastuzumab + Perjeta is continued until disease progression or unmanageable toxicity. It is noted in a footnote that maintenance trastuzumab/pertuzumab after response can be given, with concurrent endocrine therapy if estrogen receptor-positive and HER2+ metastatic disease. Under additional considerations, it is noted that patients previously treated with chemotherapy plus trastuzumab in the absence of pertuzumab in the metastatic setting may be considered for one line of therapy including both trastuzumab + pertuzumab in combination with or without cytotoxic chemotherapy. Due tot these recommendations, the use of Phesgo in metastatic breast cancer setting has been simplified.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Phesgo. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Phesgo, as well as the monitoring required for adverse events and long-term efficacy, approval requires Phesgo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Phesgo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer – Neoadjuvant or Adjuvant Therapy.** Approve for 1 year (total) if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** The medication will be used in combination with chemotherapy; OR
       Note: Examples of chemotherapy are doxorubicin, cyclophosphamide, docetaxel, paclitaxel, carboplatin.
     - **ii.** The medication is continued after chemotherapy to complete 1 year of neoadjuvant or adjuvant therapy; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

2. **Breast Cancer – Metastatic Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Phesgo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Phesgo® subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; June 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – July 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 5, 2024.