Clinical Policy Title:	pertuzumab/trastuzumab/hyaluronidase-zzxf
Policy Number:	RxA.639
Drug(s) Applied:	Phesgo®
Original Policy Date:	09/14/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. HER-2 positive Breast Cancer (must meet all)**:**

1. Diagnosis of early or metastatic HER-2 positive breast cancer;
2. Phesgo® is being prescribed in one of the following ways (a, b or c):
   a. In combination of chemotherapy and meets one of the following (i or ii):
      i. As neoadjuvant treatment for adult members 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;
      ii. As adjuvant treatment for adult members with HER2-positive early breast cancer at high risk of recurrence;
   b. In combination with docetaxel for the treatment of adult members with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or;
   c. In combination with chemotherapy for metastatic disease.

Approval Duration

All Lines of Business (except Medicare): 12 months

For post-surgery/neoadjuvant or adjuvant treatment, treatment is needed up to 18 cycles or until disease recurrence or unmanageable toxicity, whichever occurs first; For metastatic treatment, treatment is needed until disease progression or unmanageable toxicity, whichever occurs first.

II. Continued Therapy Approval

A. HER-2 positive Breast Cancer (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

For post-surgery or adjuvant treatment, treatment is needed up to 18 cycles or until disease recurrence or unmanageable toxicity, whichever occurs first; For metastatic treatment, treatment is needed until disease progression or unmanageable toxicity, whichever occurs first.

References

Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	07/14/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A was updated from "Breast Cancer" to "HER-2 positive Breast Cancer (must meet all)…"	07/05/2021	09/14/2021
Policy was reviewed.	04/12/2022	07/18/2022
Policy was reviewed.	06/29/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage.	8/28/2024	9/13/2024