

<b>Clinical Policy Title:</b>	pertuzumab/trastuzumab/hyaluronidase-zzxf
<b>Policy Number:</b>	RxA.639
<b>Drug(s) Applied:</b>	Phesgo®
<b>Original Policy Date:</b>	09/14/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	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
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This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025