

Policy Number: RXMP-27
Current Effective Date: 10/1/20YY (Medicaid), 1/1/2024 (Medicare)
Original Effective Date: 10/1/2023
Next Review/Revision Date: 7/1/2024
Plans: AlohaCare Medicaid & Medicare

PRODUCT(S):

Phesgo (pertuzumab-trastuzumab-hyaluronidase-zzxf)

HCPCS Code	HCPCS Description	How Supplied
J9316	Injection pertuzumab, trastuzumab, and hyaluronidase-zzxf 10 mg	Phesgo 1,200mg-600mg-30,000 unit/15mL SDV; 600mg-600mg-20,000 units/10mL SDV

Formulary Status:	Medical Benefit: Authorization Required Pharmacy Benefit: Refer to Drug Finder, use Carelon PA criteria
Duration of Approval:	Initial Request: 3 months COC/Reauthorization: 12 months
Quantity Limit:	See dosing information

MEDICARE PART B COVERAGE CRITERIA:

- Review using the most current Local Coverage Determination (LCD), National Coverage Determination (NCD), or Local Coverage Article (LCA) that applies to the Hawaii region. The LCD, NCD, or LCA can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>.
- No LCD/NCD/LCA found as of 9/19/2023. Review using General Coverage Criteria below.

MEDICARE PART B 90-DAY TRANSITION PERIOD:

For new Medicare members, a 90-day transition period applies. During this time, if a member is currently on an active course of the requested treatment, including when furnished by an out-of-network provider, Coverage and Step Therapy do not apply. After the first 90 days of enrollment, Coverage and Step Therapy Criteria must be met for continued coverage.

MEDICARE PART B STEP THERAPY CRITERIA:

- For new starts, Medicare Part B Step Therapy Criteria must be met in addition to Coverage Criteria before a request may be approved.
- No step therapy

GENERAL COVERAGE CRITERIA:

- Pharmacy staff: For QUEST non-ABD members with cancer, send ADRC (Aid to Disability Referral Committee) referral with chart notes through G8 CM module.
- Member is using pertuzumab-trastuzumab-hyaluronidase as a substitute anywhere that the combination of intravenous pertuzumab (J9306) and intravenous trastuzumab (J9355) are given as part of systemic therapy.
OR
 - Member has HER2-positive (HER2+) breast cancer confirmed by immunohistochemistry (IHC) is 3 + or in situ hybridization (ISH) positive and one of the following (a to c):

- a. Member has 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 and is using as neoadjuvant treatment in combination with chemotherapy
- b. Member has early breast cancer and is at high risk of recurrence and is using as adjuvant treatment in combination with chemotherapy
- c. Member has metastatic breast cancer, has not received prior anti-HER2 therapy or chemotherapy for metastatic disease is using in one of the following ways (1 or 2):
 - 1) Phesgo in combination with docetaxel (J9171)
 - 2) Phesgo alone after discontinuing combination therapy with docetaxel (J9171) and continues with Phesgo until disease progression

FDA INDICATIONS, DOSING & ADMINISTRATION:

Drug Name	Indication	Dosing/Administration
J9316, Injection pertuzumab, trastuzumab, and hyaluronidase-zzxf 10 mg [Phesgo]	HER2-positive Breast Cancer	<ul style="list-style-type: none"> Initial IM dose: 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase in 15 mL Maintenance IM dose (every 3 weeks): 600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase in 10 mL

REFERENCES:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology, Plymouth Meeting, PA: NCCN. <http://www.nccn.org/index.asp>.
 - a. Breast Cancer. V4.2023. Revised March 23, 2023.
3. Swain SM, Baselga J, Kim SB, et al. Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. N Engl J Med. 2015;372(8):724-734. doi:10.1056/NEJMoa1413513 Available at: <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1413513?articleTools=true>

CHANGE HISTORY:

9/19/23 DS/PH: New