

## Drug Policy:

# Perjeta™ (pertuzumab) and Phesgo™ (pertuzumab, trastuzumab, and hyaluronidase-zzxf)

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| <b>POLICY NUMBER</b><br>UM ONC_1216   | <b>SUBJECT</b><br>Perjeta™ (pertuzumab) and Phesgo™ (pertuzumab, trastuzumab, and hyaluronidase-zzxf) | <b>DEPT/PROGRAM</b><br>UM Dept  | <b>PAGE 1 OF 4</b>  |
| <b>DATES COMMITTEE REVIEWED</b><br>09/12/12, 02/12/14, 12/17/15, 07/19/16, 11/18/16, 04/27/17, 05/07/18, 05/08/19, 08/14/19, 12/11/19, 03/11/20, 04/08/20, 07/08/20, 08/12/20, 01/13/21, 03/10/21, 04/14/21 | <b>APPROVAL DATE</b><br>April 14, 2021  | <b>EFFECTIVE DATE</b><br>April 30, 2021                               | <b>COMMITTEE APPROVAL DATES</b><br>(latest version listed last)<br>09/12/12, 02/12/14, 12/17/15, 07/19/16, 11/18/16, 04/27/17, 05/07/18, 05/08/19, 08/14/19, 12/11/19, 03/11/20, 04/08/20, 07/08/20, 08/12/20, 01/13/21, 03/10/21, 04/14/21 |
| <b>PRIMARY BUSINESS OWNER:</b> UM   |   | <b>COMMITTEE/BOARD APPROVAL</b><br>Utilization Management Committee   |   |
| <b>URAC STANDARDS</b><br>HUM 1  | <b>NCQA STANDARDS</b><br>UM 2   | <b>ADDITIONAL AREAS OF IMPACT</b>                                     |   |
| <b>CMS REQUIREMENTS</b>   | <b>STATE/FEDERAL REQUIREMENTS</b>   | <b>APPLICABLE LINES OF BUSINESS</b><br>Commercial, Exchange, Medicaid |   |

## I. PURPOSE

To define and describe the accepted indications for Perjeta (pertuzumab) and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## II. INDICATIONS FOR USE/INCLUSION CRITERIA

#### **A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines shall follow NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. [Kanjinti + Perjeta and Ogviri + Perjeta are the PREFERRED options when a combination of trastuzumab and pertuzumab is used/indicated.](#)
5. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
6. When available, generic alternatives are preferred over brand-name drugs.

#### **B. Breast Cancer (HER-2 + defined by IHC 3+ or FISH positive)**

1. For metastatic HER-2+ breast cancer
  - a. In combination with trastuzumab and docetaxel or paclitaxel as first line therapy **OR**
  - b. In combination with trastuzumab as a continuation of maintenance therapy after completion of treatment with taxane + pertuzumab + trastuzumab **OR**
  - c. In combination with trastuzumab with or without cytotoxic therapy (e.g., vinorelbine or taxane) as second/subsequent line if previously treated with trastuzumab and chemotherapy **AND** is pertuzumab naïve.
2. Neoadjuvant or adjuvant therapy for HER-2+ breast cancer
  - a. Perjeta (pertuzumab) may be used in combination with Trastuzumab for neoadjuvant or adjuvant chemotherapy as follows:
    - i. Perjeta may be used in the neoadjuvant (pre-operative) setting for members with stage II **OR** node positive disease.
    - ii. Perjeta (pertuzumab) may be used for adjuvant (post-operative) use in members who did not receive neoadjuvant therapy and have node positive disease **OR** did receive neoadjuvant therapy and did not have any residual disease in the breast and/or axillary lymph nodes at surgery.
    - iii. Note: If neoadjuvant therapy was given, and there is evidence of residual disease in the breast and or axillary nodes, the Preferred drug per NCH Policy & NCH Pathway is Kadcyła (ado-trastuzumab).
  - b. Perjeta (pertuzumab) may be used in combination with any of the following neoadjuvant or adjuvant regimens:
    - i. In combination with trastuzumab and paclitaxel/docetaxel following AC (doxorubicin and cyclophosphamide)
    - ii. In combination with TCH (docetaxel, carboplatin, and trastuzumab).
  - c. The preferred agents, per NCH Policies for neoadjuvant and adjuvant treatment of early stage or locally advanced HER-2 positive breast cancer include the following:

| Disease characteristics                  | Neoadjuvant Preferred Rx                | Adjuvant Preferred Rx<br><i>No Residual Disease after Neoadjuvant Therapy</i> | Adjuvant Preferred Rx<br><i>Residual Disease present after Neoadjuvant Therapy</i> | Adjuvant Preferred Rx<br><i>No Neoadjuvant Therapy given</i>  |
|--|---|---|--|---|
| NODE negative or Stage I disease         | Trastuzumab + Chemo                     | Additional Trastuzumab; Additional Chemo if not completed pre-op              | Kadcyla (ado-trastuzumab emtansine)  | Trastuzumab + Chemo then additional Trastuzumab   |
| NODE positive or Stage II or III disease | Trastuzumab + Pertuzumab + Chemotherapy | Additional Trastuzumab + Pertuzumab; Additional Chemo if not completed pre-op | Kadcyla (ado-trastuzumab emtansine)  | For Node + disease only Trastuzumab + Pertuzumab + Chemotherapy, then additional Trastuzumab + Pertuzumab |

### III. EXCLUSION CRITERIA

- The member has HER-2 negative disease.
- The member has node negative disease.
- The total treatment duration, in the non-metastatic setting, exceeds a maximum of 52 weeks or 1 year (the equivalent of 17 three-week cycles). The above duration does not include necessary therapy interruptions, e.g., due to surgery, and/or post-operative recovery.
- Dosing exceeds single dose limit of Perjeta (pertuzumab) 840 mg (initial dose) or 420 mg (subsequent dose) every 3 weeks or Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) 1200 mg (initial dose) and 600 mg (subsequent dose).
- Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

### IV. MEDICATION MANAGEMENT

- Please refer to the FDA label/package insert for details regarding these topics.

### V. APPROVAL AUTHORITY

- Review – Utilization Management Department
- Final Approval – Utilization Management Committee

### VI. ATTACHMENTS

- None

### VII. REFERENCES

- Piccart et al, APHINITY trial 6 year follow up, J Clin Oncol 2021, February 4, 2021. DOI: <https://doi.org/10.1200/JCO.20.01204>.
- von Minckwitz G, Procter M, de Azambuja E, et al: Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer. N Engl J Med 377:122-131, 2017. (APHINITY Trial).

- C. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) prescribing information. Genentech, Inc. South San Francisco, CA 2020.
- D. Perjeta prescribing information. Genentech USA, Inc. South San Francisco, CA 2020.
- E. Clinical Pharmacology Elsevier Gold Standard 2021.
- F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.