Drug Policy:

Perjeta™ (pertuzumab) and Phesgo

POLICY NUMBER UM ONC_1216	SUBJECT Perjeta™ (pertuzumab) and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 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	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 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	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** 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. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

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

NOTE: Per NCH Policy, whenever [pertuzumab + trastuzumab] is requested, Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) is the preferred product unless there is a contraindication/intolerance to Phesgo.

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 or HER-2+ breast cancer
   a. For locally advanced, inflammatory, or early stage breast cancer for ONE of the following neoadjuvant or adjuvant treatments:
      i. Pertuzumab + trastuzumab + chemotherapy is indicated only in members with a tumor size 2 cm or higher, node positive disease, or ER/PR negative disease AND
      ii. Neoadjuvant pertuzumab + trastuzumab + chemotherapy will be used either:
         - In combination with trastuzumab and paclitaxel or docetaxel with or without previous or subsequent therapy with an anthracycline (epirubicin or doxorubicin) based regimen OR
         - In combination with TCH (docetaxel, carboplatin, and trastuzumab) regimen
      iii. Adjuvant pertuzumab + trastuzumab +/- chemotherapy may be used if:
         - Member has axillary node positive disease AND
         - No neoadjuvant therapy was given AND pertuzumab is being given in combination with TCH OR in combination with paclitaxel or docetaxel following AC regimen OR
         - As a continuation of maintenance trastuzumab/pertuzumab for up to 52 weeks of total therapy if neoadjuvant therapy was given and there was no residual disease found in the breast/axillary nodes at surgery OR if neoadjuvant therapy was not given and member was found to have axillary node positive disease
      iv. After neoadjuvant therapy, if there is evidence of residual disease in the breast and or axillary nodes, then the Preferred adjuvant drug is Kadcyla (ado-trastuzumab emtansine).

v. NOTE: The preferred agents, per NCH Policies for neoadjuvant and adjuvant treatment of early stage or locally advances HER-2 positive breast cancer include the following:

Disease characteristics	Neoadjuvant Preferred Rx	Adjuvant Preferred Rx *No Residual Disease after Neoadjuvant Therapy*	Adjuvant Preferred Rx *Residual Disease present after Neoadjuvant Therapy*	Adjuvant Preferred Rx *No Neoadjuvant Therapy given*
< 2 cm AND ER/PR + AND NODE negative	Trastuzumab + Chemo	Additional Trastuzumab; Additional Chemo if not completed pre-op	Kadcyla (ado-trastuzumab emtansine)	Trastuzumab + Chemo then additional Trastuzumab
>2 cm OR ER/PR negative OR NODE positive	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

A. The member has HER-2 negative disease.

B. 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.

C. 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).

D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) prescribing information. Genentech, Inc. South San Francisco, CA 2020.

B. Perjeta prescribing information. Genentech USA, Inc. South San Francisco, 2020.
C. Clinical Pharmacology Elsevier Gold Standard. 2020.
D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
F. Genentech USA, Inc. South San Francisco, 2020.