

POLICY NUMBER UM ONC_1216	SUBJECT Perjeta™ (pertuzumab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
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	APPROVAL DATE July 8, 2020	EFFECTIVE DATE July 31, 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	
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 All	

I. PURPOSE

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

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- a. 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**
- b. 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**
- c. 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**
- d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- e. When available, generic alternatives are preferred over brand-name drugs.

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

- a. For metastatic HER-2+ breast cancer
 - i. In combination with trastuzumab and docetaxel or paclitaxel as first line therapy **OR**
 - ii. In combination with trastuzumab as a continuation of maintenance therapy after completion of treatment with taxane + pertuzumab + trastuzumab **OR**



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- iii. 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.
- b. Neoadjuvant or adjuvant therapy of HER-2+ breast cancer
 - i. For locally advanced, inflammatory, or early stage breast cancer for **ONE** of the following neoadjuvant or adjuvant treatments:
 - A. 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**
 - B. Neoadjuvant pertuzumab + trastuzumab + chemotherapy will be used either:
 - 1) In combination with trastuzumab and paclitaxel or docetaxel with or without previous or subsequent therapy with an anthracycline (epirubicin or doxorubicin) based regimen **OR**
 - 2) In combination with TCH (docetaxel, carboplatin, and trastuzumab) regimen
 - C. Adjuvant pertuzumab + trastuzumab +/- chemotherapy may be used if:
 - 1) No neoadjuvant therapy was given **AND** is being given in combination with TCH **OR** in combination with paclitaxel or docetaxel following AC regimen **OR**
 - 2) 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.
 - D. After neoadjuvant therapy, if there is evidence of residual disease in the breast and or axillary nodes, then the Preferred adjuvant drug is Kadcylla (ado-trastuzumab emtansine).
 - E. **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 <i>No Residual Disease after Neoadjuvant Therapy</i>	Adjuvant Preferred Rx <i>Residual Disease present after Neoadjuvant Therapy</i>	Adjuvant Preferred Rx <i>No Neoadjuvant Therapy given</i>
< 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)	Trastuzumab + Pertuzumab + Chemotherapy, then additional Trastuzumab + Pertuzumab



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III. EXCLUSION CRITERIA

1. The member has HER-2 negative disease.
2. 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.
3. Dosing exceeds single dose limit of Perjeta (pertuzumab) 840 mg (initial dose) or 420 mg (subsequent dose) every 3 weeks.
4. 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

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Perjeta prescribing information. Genentech USA, Inc. South San Francisco, 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. Genentech USA, Inc. South San Francisco, 2020.