Drug Policy:

Trastuzumab Products and Phesgo

POLICY NUMBER UM ONC_1134	**SUBJECT** Trastuzumab products (Herceptin, Herceptin Hylecta, Ogivri, Herzuma, Ontruzant, Kanjinti, Trazimera) and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 07/22/11, 06/12/13, 07/23/14, 04/13/16, 07/26/16, 11/08/16, 09/13/17, 12/13/17, 11/14/18, 01/09/19, 03/13/19, 07/10/19, 09/11/19, 12/11/19, 01/08/20, 02/12/20, 03/11/20, 04/08/20, 06/10/20, 07/08/20, 08/27/20	**APPROVAL DATE** August 27, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 07/22/11, 06/12/13, 07/23/14, 04/13/16, 07/26/16, 11/08/16, 09/13/17, 12/13/17, 11/14/18, 01/09/19, 03/13/19, 07/10/19, 09/11/19, 12/11/19, 01/08/20, 02/12/20, 03/11/20, 04/08/20, 06/10/20, 07/08/20, 08/27/20
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 Trastuzumab products [Herceptin (trastuzumab), Herceptin Hylecta (trastuzumab hyaluronidase), Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp)] 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.
6. Kanjinti (trastuzumab-anns) and Trazimera (trastuzumab-qyyp) are the PREFERRED medications whenever Herceptin (trastuzumab) or Herceptin Hylecta (trastuzumab hyaluronidase) is requested.
7. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) is the preferred product when a combination of pertuzumab and trastuzumab is indicated and supported by NCH Clinical Policies.
8. Non-preferred trastuzumab will be approved only if there is a contraindication/intolerance to the PREFERRED medication.

B. HER-2 Positive Breast Cancer

1. Herceptin (trastuzumab), Herceptin Hylecta (trastuzumab hyaluronidase), Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Kanjinti, or Trazimera (trastuzumab-qyyp) is being used as ONE of the following:
    a. In combination with chemotherapy with or without Perjeta (pertuzumab) for neoadjuvant or adjuvant therapy.
        i. NOTE: [Pertuzumab + Trastuzumab] is indicated only in patients with a tumor size 2 cm or higher, node positive disease or ER/PR negative disease. The combination may be used in the neoadjuvant setting. In the adjuvant setting it may be used if :
            - No neoadjuvant therapy was given, OR
            - Neoadjuvant therapy was given and there was no residual disease found in the breast/axillary nodes at surgery.
        ii. NOTE: If neoadjuvant therapy was given, and there is evidence of residual disease in the breast and or axillary nodes, then the Preferred drug per NCH Policy & NCH Pathway is Kadcyla (ado-trastuzumab).

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

b. First line or subsequent line therapy for recurrent or metastatic HER-2 positive breast cancer:

i. In combination with Novaldex (tamoxifen), Faslodex (fulvestrant), or an aromatase inhibitor for a member whose disease is also ER/PR positive OR

ii. In combination with pertuzumab and a taxane, Taxotere (docetaxel) or Taxol (paclitaxel), regardless of the ER/PR status OR

iii. In combination with other single agent chemotherapy agents e.g. vinorelbine.

C. HER-2 Positive Gastric/Esophageal and Esophagogastric Junction Cancers

1. The member has a diagnosis of recurrent/metastatic gastric or esophageal or esophagogastric junction cancer and the cancer is HER-2 positive (defined as IHC 3+ or FISH positive) AND
2. Herceptin (trastuzumab), Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Kanjinti (trastuzumab-anns), or Trazimera (trastuzumab-qyyp) is being used in combination with cisplatin oroxaliplatin and 5-fluorouracil (or capecitabine) as first line therapy.

III. EXCLUSION CRITERIA

A. Herceptin (trastuzumab)/Ogivri (trastuzumab-dkst)/Herzuma (trastuzumab-pkrb)/Ontruzant (trastuzumab-dttb)/Kanjinti (trastuzumab-anns)/Trazimera (trastuzumab-qyyp) use in gastric or gastroesophageal junction cancer after disease progression with first line therapy containing trastuzumab.

B. Continuation of trastuzumab after disease progression on trastuzumab-based therapy in HER-2 positive esophageal, gastroesophageal, and gastric adenocarcinomas.

C. Dosing exceeds single dose limit of trastuzumab 8 mg/kg for the loading dose, 6mg/kg for subsequent doses when given every 3 weeks; 4 mg/kg for the loading dose and 2 mg/kg for the subsequent doses, when trastuzumab is being given weekly.

D. Dosing exceeds single dose limit of Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) 1200 mg (initial dose) and 600 mg (subsequent dose).

E. Total treatment duration exceeds a maximum 52 weeks or 1 year (the equivalent of 17 three week cycles) in non-metastatic HER-2 positive breast cancer. The above duration does not include any necessary therapy interruption, e.g. due to breast surgery and post-operative recovery.

F. Indication is 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. Herceptin Hylecta , prescribing information. Genentech, Inc. South San Francisco, CA. 2019.

C. Herceptin, prescribing information. Genentech, Inc. South San Francisco, CA. 2020.

D. Trazimera prescribing information. Pfizer Belgium NV, Belgium. 2020

E. Ogivri prescribing information. Mylan GmbH Zurich, Switzerland. 2020

F. Ontruzant prescribing information. Merck & Co., Inc., Whitehouse Station, NJ 2020

G. Herzuma prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA 2020

H. Kanjinti prescribing information. Amgen020

I. Clinical Pharmacology Elsevier Gold Standard. 2020

J. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020

K. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.