POLICY NUMBER UM ONC_1238	SUBJECT Kadcyla™ (ado-trastuzumab emtansine)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 04/10/13, 05/17/13, 07/24/14, 12/18/15, 12/20/16, 11/01/17, 09/04/18, 08/14/19, 12/11/19, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 04/10/13, 05/17/13, 07/24/14, 12/18/15, 12/20/16, 11/01/17, 09/04/18, 08/14/19, 12/11/19, 04/08/20	
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 Kadcyla (ado-trastuzumab emtansine) 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: http://pathways.newcenturyhealth.com **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

a. For Metastatic HER-2 positve Breast cancer: Kadcyla (ado-trastuzumab emtansine) is being used as a single agent in members with metastatic HER-2 positive breast cancer who have experienced disease progression after first line therapy with a taxane + trastuzumab + pertuzumab.

b. For Adjuvant Therapy of HER-2 positive breast cancer: Patients with stage I-III HER-2 positive breast cancer, who have undergone neoadjuvant therapy, and have residual disease in the breast and/or axillary nodes. See Table below.

Disease characteristics All Patients Stages I-III	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	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	Trastuzumab + Pertuzumab + Chemotherapy, then additional Trastuzumab + Pertuzumab

III. EXCLUSION CRITERIA

1. Concurrent use with trastuzumab, lapatinib, pertuzumab, or other chemotherapy; endocrine therapy may continue concurrently if indicated.
2. Disease progression while taking Kadcyla (ado-trastuzumab emtansine).
3. Dosing exceeds single dose limit of Kadcyla (ado-trastuzumab emtansine) 3.6 mg/kg.
4. Dosing exceeds maximum duration of 14 cycles for adjuvant treatment.
5. 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. Ado-trastuzumab emtansine prescribing information. Genentech Inc. San Francisco, CA. 2019.
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. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.