Drug Policy:

Tykerb™ (lapatinib)

POLICY NUMBER UM ONC_1233	SUBJECT Tykerb™ (lapatinib)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 12/12/12, 12/11/13, 03/16/15, 03/27/15, 05/24/16, 03/07/17, 03/08/18, 03/13/19, 12/11/19, 03/11/20, 01/13/21, 11/15/21	APPROVAL DATE November 15, 2021	EFFECTIVE DATE November 29, 2021	COMMITTEE APPROVAL DATES 12/12/12, 12/11/13, 03/16/15, 03/27/15, 05/24/16, 03/07/17, 03/08/18, 03/13/19, 12/11/19, 03/11/20, 01/13/21, 11/15/21	
PRIMARY BUSINESS OWNER: UM		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 Tyrosine kinase inhibitors in the treatment of recurrent/metastatic her-2-neu (+) breast cancer, specifically Tykerb (lapatinib) 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

1. NOTE: Per NCH Policy and NCH Pathway, Tykerb (lapatinib) is preferred over Tukysa (tucatinib) due to lack of level I evidence showing superiority of Tukysa (tucatininb) over Tykerb (lapatinib) for metastatic HER-2 + breast cancer.
2. The member has recurrent/metastatic HER-2 positive breast cancer which has progressed on a Taxane and Trastuzumab and Tykerb (lapatinib) is being used as subsequent line of therapy in ANY of the following:
   a. In combination with capecitabine and/or trastuzumab OR
   b. In combination with an aromatase inhibitor for postmenopausal/premenopausal women treated with ovarian ablation/suppression with hormone receptor-positive tumors.

III. EXCLUSION CRITERIA

A. Member has disease progression while taking Tykerb (lapatinib).

B. Dosing exceeds single dose limit of Tykerb (lapatinib) 1500mg.

C. Treatment exceeds the maximum limit of 180 (250 mg) tablets/month.

D. Investigational use of Tykerb (lapatinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

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

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M. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

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