

Drug Policy:

Tykerb™ (lapatinib)

POLICY NUMBER UM ONC_1233	SUBJECT Tykerb™ (lapatinib)	DEPT/PROGRAM UM Dept	PAGE 1 OF 3
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	APPROVAL DATE January 13, 2021	EFFECTIVE DATE January 29, 2021	COMMITTEE APPROVAL DATES (latest version listed last) 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
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 \(tucatinib\) 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. 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. A phase III randomized comparison of lapatinib plus capecitabine versus capecitabine alone in women with advanced breast cancer that has progressed on trastuzumab: updated efficacy and biomarker analyses. Cameron D, Casey M, Press M, Lindquist D, Pienkowski T, Romieu CG, Chan S, Jagiello-Gruszfeld A, Kaufman B, Crown J, Chan A, Campone M, Viens P, Davidson N, Gorbounova V, Raats JI, Skarlos D, Newstat B, Roychowdhury D, Paoletti P, Oliva C, Rubin S, Stein S, Geyer CE, Breast Cancer Res Treat. 2008;112(3):533. Epub 2008 Jan 11.

- B. Lapatinib plus capecitabine for HER2-positive advanced breast cancer. Geyer CE, Forster J, Lindquist D, Chan S, Romieu CG, Pienkowski T, Jagiello-Gruszfeld A, Crown J, Chan A, Kaufman B, Skarlos D, Campone M, Davidson N, Berger M, Oliva C, Rubin SD, Stein S, Cameron D, N Engl J Med. 2006;355(26):2733.
- C. Lapatinib plus capecitabine in women with HER-2-positive advanced breast cancer: final survival analysis of a phase III randomized trial. Cameron D, Casey M, Oliva C, Newstat B, Imwalle B, Geyer CE, Oncologist. 2010;15(9):924. Epub 2010 Aug 24.
- D. Randomized study of Lapatinib alone or in combination with trastuzumab in women with ErbB2-positive, trastuzumab-refractory metastatic breast cancer. Blackwell KL, Burstein HJ, Storniolo AM, Rugo H, Sledge G, Koehler M, Ellis C, Casey M, Vukelja S, Bischoff J, Baselga J, O'Shaughnessy J, J Clin Oncol. 2010;28(7):1124. Epub 2010 Feb 1.
- E. Overall survival benefit with lapatinib in combination with trastuzumab for patients with human epidermal growth factor receptor 2-positive metastatic breast cancer: final results from the EGF104900 Study. Blackwell KL, Burstein HJ, Storniolo AM, Rugo HS, Sledge G, Aktan G, Ellis C, Florance A, Vukelja S, Bischoff J, Baselga J, O'Shaughnessy J, J Clin Oncol. 2012;30(21):2585. Epub 2012 Jun 11.
- F. Johnston S, et al. Lapatinib combined with letrozole versus letrozole and placebo as first-line therapy for postmenopausal hormone receptor-positive metastatic breast cancer. J Clin Oncol. 2009 Nov 20;27(33):5538-46.
- G. Charles E. Geyer, et al. Lapatinib plus Capecitabine for HER2-Positive Advanced Breast Cancer. N Engl J Med 2006; 355:2733-2743.
- H. Tykerb prescribing information. Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 2020.
- 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.
- L. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs . Bethesda, MD. 2020.