

Drug Policy:

Tukysa™ (tucatinib)

POLICY NUMBER UM ONC_1401	SUBJECT Tukysa™ (tucatinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 05/13/20, 07/08/20, 07/14/21, 11/15/21, 01/12/22, 03/09/22	APPROVAL DATE March 9, 2022	EFFECTIVE DATE March 25, 2022	COMMITTEE APPROVAL DATES 05/13/20, 07/08/20, 07/14/21, 11/15/21, 01/12/22, 03/09/22	
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 Tukysa (tucatinib) 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 applicable, generic alternatives are preferred over brand-name drugs.

B. Breast Carcinoma

1. **NOTE:** Per NCH Pathway & NCH Policy, Tukysa (tucatinib) is non-preferred in members with metastatic HER2 positive breast cancer, except in members with brain metastases. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with Tukysa (tucatinib) compared to another anti-HER2 based regimen. Please refer to NCH Pathway for the preferred treatments recommended for use in metastatic HER2 positive breast cancer.
2. Tukysa (tucatinib) may be used in members with metastatic HER2 positive breast cancer and brain metastases **OR** in members without brain metastases if there is disease progression, contraindication, or intolerance to 3 or more prior anti HER-2 therapies in the metastatic setting including Kadcyla (ado- trastuzumab) and a trastuzumab containing regimen [e.g., Trastuzumab + Pertuzumab/Lapatinib +/- Chemotherapy] **AND**
3. Tukysa (tucatinib) will be used in combination with Herceptin (trastuzumab)/trastuzumab biosimilar product (i.e., Kanjinti or Ogivri) + Xeloda (capecitabine).

III. EXCLUSION CRITERIA

- A. Disease progression on Tukysa (tucatinib) or another oral tyrosine kinase inhibitor [e.g., Tykerb (lapatinib)], unless time of Tykerb (lapatinib) therapy was received ≥ 12 months ago.
- B. Dosing exceeds single dose limit of Tukysa (tucatinib) 300 mg.
- C. Treatment exceeds the maximum limit of 30 (50 mg) or 120 (150 mg) tablets/month.
- D. Investigational use of Tukysa (tucatinib) 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

- A. Murthy RK, et al. Tucatinib, Trastuzumab, and Capecitabine for HER2-Positive Metastatic Breast Cancer. *N Engl J Med.* 2020 Feb 13;382(7):597-609.
- B. Tukysa prescribing information. Seattle Genetics, Inc. Bothell, WA 2020.
- C. Clinical Pharmacology Elsevier Gold Standard 2022.
- D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.
- E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.
- F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2022.
- G. 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.
- H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.