VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tukysa Prior Authorization Policy
- Tukysa® (tucatinib tablets –Seagan)

REVIEW DATE: 05/18/2022; selected revision 06/22/2022 and 01/25/2023

OVERVIEW

Tukysa, a kinase inhibitor, is indicated for the following uses:[1]

- **Breast cancer**, in combination with trastuzumab and capecitabine, for the treatment of adults with advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- **Colorectal cancer**, in combination with trastuzumab, for the treatment of adults with RAS wild-type HER2-positive unresectable or metastatic disease that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
  This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Guidelines

Tukysa is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):

- **Breast Cancer:** NCCN guidelines (version 4.2022 – June 21, 2022) recommend Tukysa + trastuzumab + capecitabine as a third-line and beyond option (category 1) for the treatment of recurrent unresectable (local or regional) or Stage IV HER2-positive disease in patients with both systemic and central nervous system (CNS) progression.[2] There is a footnote that states it may be given in the second-line setting. Perjeta® (pertuzumab intravenous infusion) + trastuzumab + docetaxel (category 1) and Perjeta + trastuzumab + paclitaxel (category 2A) are recommended first-line regimens. Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion) [category 1] and Kadcyla® (ado-trastuzumab emtansine intravenous infusion) [category 2A] are recommended second-line agents.
- **Colon Cancer and Rectal Cancer:** NCCN colon cancer guidelines (version 3.2022 – January 25, 2023) and NCCN rectal cancer guidelines (version 4.2022 – January 25, 2023) recommend Tukysa in combination with trastuzumab as a primary or subsequent treatment option for advanced or metastatic HER2-amplified, *RAS* and *BRAF* wild type disease (category 2A)[3,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tukysa. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tukysa is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer.** Approve for 1 year if the patient meets ALL of the criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic breast cancer; AND
   - **C)** Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **D)** Patient has received at least one prior anti-HER2-based regimen in the metastatic setting; AND
     Note: Examples of anti-HER2-based regimens include Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Kadcyla (ado-trastuzumab emtansine intravenous infusion), capecitabine + trastuzumab or lapatinib tablets, trastuzumab + lapatinib tablets, Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion), trastuzumab + docetaxel or vinorelbine, Nerlynx (neratinib tablets) + capecitabine, and Margenza (margetuximab-cmkb intravenous infusion) + chemotherapy (capecitabine, Halaven [eribulin intravenous infusion], gemcitabine, or vinorelbine).
   - **E)** The medication is used in combination with trastuzumab and capecitabine.

2. **Colon and Rectal Cancer**. Approve for 1 year if the patient meets ALL of the criteria (A, B, C, D, E, F, G, and H):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable or metastatic disease; AND
   - **C)** Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **D)** Patient's tumor or metastases are wild-type *RAS* (*KRAS* wild-type and *NRAS* wild-type); AND
   - **E)** Patient has been previously treated with a fluoropyrimidine; AND
     Note: Examples of a fluoropyrimidine include capecitabine, 5-fluorouracil (5-FU).
   - **F)** Patient has been previously treated with oxaliplatin; AND
   - **G)** Patient has been previously treated with irinotecan AND
   - **H)** The medication is used in combination with trastuzumab.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tukysa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tukysa® tablets [prescribing information]. Bothell, WA: Seagen; January 2023.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – May 7, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 16, 2022.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – January 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 25, 2023.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – January 25, 2023). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 25, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/22/2020
Annual Revision	No criteria changes. The Note regarding examples of anti-HER2-based regimens was revised to change "trastuzumab + capecitabine" to "capecitabine + trastuzumab or lapatinib tablets". Additionally, the following regimens were added to the Note: Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion), trastuzumab + docetaxel or vinorelbine, Nerlynx (neratinib tablets) + capecitabine, Margenza (margetuximab-cmkb) + chemotherapy (capecitabine, Halaven [eribulin intravenous infusion], gemcitabine, or vinorelbine).	04/28/2021
Annual Revision	**Breast Cancer:** A requirement that patient is ≥ 18 years of age was added. The requirement that the patient has "advanced unresectable or metastatic" disease was reworded to patient has "recurrent or metastatic" breast cancer.	05/18/2022
Selected Revision	**Breast Cancer:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Selected Revision	**Colon and Rectal Cancer:** Conditions of approval and criteria added based on FDA approval for this indication.	01/25/2023