

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tukysa Prior Authorization Policy

- Tukysa® (tucatinib tablets –Seagan)

REVIEW DATE: 05/15/2024

OVERVIEW

Tukysa, a kinase inhibitor, is indicated for the following uses in adults:¹

- **Breast cancer**, in combination with trastuzumab and capecitabine, for the treatment of 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 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):

- **Biliary Tract Cancers:** NCCN guidelines (version 2.2024 – April 19, 2024) recommend Tukysa + trastuzumab as “useful in certain circumstances” as subsequent line therapy for unresectable and metastatic disease if there is disease progression.²
- **Breast Cancer:** NCCN guidelines (version 2.2024 – March 11, 2024) recommend Tukysa + trastuzumab + capecitabine in the third-line and beyond setting as a “preferred” regimen (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.³ 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 “preferred” first-line regimens. Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion) [category 1] is a “preferred” second-line agent.
- **Colon Cancer and Rectal Cancer:** NCCN colon cancer guidelines (version 2.2023 – April 25, 2023) and NCCN rectal cancer guidelines (version 2.2024 – April 30, 2024) 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) in a variety of different clinical scenarios.^{4,5}

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

05/15/2024

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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 following (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; Kadcyra (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 or Rectal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
 - 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)-amplified disease; AND
 - D) Patient's tumor or metastases are wild-type *RAS* (*KRAS* wild-type and *NRAS* wild-type); AND
 - E) The medication is used in combination with trastuzumab.

Other Uses With Supportive Evidence

- 3. Biliary Tract Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
 - 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 has tried at least one systemic regimen; AND
Note: Examples of a systemic regimen include one or more of the following medications: Imfinzi (durvalumab intravenous infusion), gemcitabine, cisplatin, Keytruda (pembrolizumab intravenous infusion), capecitabine, oxaliplatin, albumin-bound paclitaxel.
 - E) 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 Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 2.2024 – April 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 13, 2024.

3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 13, 2024.
4. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 13, 2024.
5. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 13, 2024.