PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/07/2023

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tukysa, a kinase inhibitor, is indicated for the following uses:[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 in adults.
- **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 in adults.
  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 4.2023 – March 23, 2023) 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.[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] is a recommended second-line agent.

- **Colon Cancer and Rectal Cancer:** NCCN colon cancer guidelines (version 2.2023 – April 25, 2023) and NCCN rectal cancer guidelines (version 3.2023 – May 26, 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) in a variety of different clinical scenarios.[3,4]

POLICY STATEMENT

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

- **Tukysa® (tucatinib tablets (Seagan)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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, 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.

CONDITIONS NOT COVERED

- **Tukysa® (tucatinib tablets (Seagan)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Tukysa® tablets [prescribing information]. Bothell, WA: Seagen; January 2023.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – March 23, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 2, 2023.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 6, 2023.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – May 26, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 6, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	**Colon and Rectal Cancer:** The requirement that the patient has human epidermal growth factor receptor 2 (HER2)-positive disease was reworded to "HER2-amplified disease." The requirements that the patient has previously been treated with a fluoropyrimidine with a note of examples of fluoropyrimidine; oxaliplatin; and irinotecan were removed.	06/07/2023