UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1317-7
Program	Prior Authorization/Notification
Medication	Tukysa® (tucatinib)
P&T Approval Date	6/2020, 11/2021, 11/2022, 3/2023, 3/2024, 3/2025, 3/2026
Effective Date	6/1/2026

1. Background:

Tukysa (tucatinib) is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. Tukysa is also indicated in combination with trastuzumab for the treatment of adult patients with *RAS* wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

The National Cancer Comprehensive Network (NCCN) recommends the use of Tukysa for the treatment of central nervous system cancers (limited and extensive brain metastases) when used in combination with capecitabine and trastuzumab in patients with HER2 positive breast cancer if previously treated with one or more anti-HER2-based regimens. The NCCN also recommends the use of Tukysa in combination with trastuzumab for the treatment of advanced or metastatic colorectal cancer (HER2-amplified and *RAS* and *BRAF* wild-type) if intensive therapy not recommended as well as in combination with trastuzumab as subsequent therapy for HER2-positive unresectable, resected gross residual (R2), or metastatic biliary tract cancers.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Tukysa** will be approved based on the following criterion**:**

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Breast Cancer</u>

1. **Initial Authorization**

   a. **Tukysa** will be approved based on **all** of the following criteria:

      (1) Diagnosis of breast cancer

      -AND-

      (2) Disease is **one** of the following:

         (a) Advanced unresectable
         (b) Metastatic

      -AND-

      (3) Disease is human epidermal growth factor receptor 2 (HER2)-positive

      -AND-

      (4) Patient has been previously treated with an anti-HER2-based regimen in the metastatic setting (e.g., trastuzumab [Kanjinti, Ogivri, Trazimera], pertuzumab [Perjeta], ado-trastuzumab emtansine [Kadcyla])

      -AND-

      (5) Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera) and capecitabine (Xeloda)

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Tukysa** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on **Tukysa** therapy

      Authorization will be issued for 12 months.

C. CNS Cancers

1. **Initial Authorization**

   a. **Tukysa** will be approved based on **all** of the following criteria:

      (1) Diagnosis of brain metastases

      -AND-

      (2) Patient has HER2 positive breast cancer

-AND-

(3) Patient has been previously treated with an anti-HER2-based regimen in the metastatic setting (e.g., trastuzumab [Kanjinti, Ogivri, Trazimera], pertuzumab [Perjeta], ado-trastuzumab emtansine [Kadcyla])

-AND-

(4) Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera) and capecitabine (Xeloda)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tukysa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Tukysa** therapy

Authorization will be issued for 12 months.

D. Colorectal Cancer

1. **Initial Authorization**

a. **Tukysa** will be approved based on **all** of the following criteria:

(1) Diagnosis of unresectable, advanced or metastatic colorectal cancer (HER2-amplified and RAS and BRAF wild-type)

-AND-

(2) Disease is human epidermal growth factor receptor 2 (HER2)-positive

-AND-

(3) **One** of the following:

(a) Patient has previously been treated with **one** of the following regimens:

i. Fluoropyrimidine-based chemotherapy
ii. Oxaliplatin-based chemotherapy
iii. Irinotecan-based chemotherapy

-OR-

(b) Patient is not appropriate for intensive therapy

-AND-

(4) Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tukysa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Tukysa** therapy

Authorization will be issued for 12 months.

D. Biliary Tract Cancers

1. Initial Authorization

a. Tukysa will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Gallbladder Cancer
(b) Intrahepatic cholangiocarcinoma
(c) Extrahepatic cholangiocarcinoma

-AND-

(2) Disease is human epidermal growth factor receptor 2 (HER2)-positive

-AND-

(3) Disease is one of the following:

(a) Unresectable
(b) Resected gross residual (R2)
(c) Metastatic

-AND-

(3) Patient has received at least one prior systemic therapy

-AND-

(4) Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tukysa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tukysa therapy

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Tukysa® [package insert]. Bothell, WA: Seattle Genetics, Inc. January 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed February 12, 2025.

Program	Prior Authorization/Notification – Tukysa (tucatinib)
Change Control	
6/2020	New program.
11/2021	Annual review. Added criteria for CNS cancers according to NCCN compendia. Updated background and references.
11/2022	Annual review. Added state mandate. Updated references.
3/2023	Updated background and added criteria for colorectal cancer per FDA label. Updated references.
3/2024	Annual review. No changes to clinical criteria.
3/2025	Annual review. Added criteria for NCCN recommended use of Tukysa in biliary tract cancers. Updated background and references.
3/2026	Annual review. Changed wording for CNS cancers.