



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/21/2020
LAST REVIEW DATE: 5/20/2021
LAST CRITERIA REVISION DATE: 5/20/2021
ARCHIVE DATE:

TUKYSA™ (tucatinib)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**



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Criteria:

- **Criteria for initial therapy:** Tukysa (tucatinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - a. In combination with trastuzumab and capecitabine for treatment of advanced unresectable or metastatic hormone receptor negative or hormone receptor positive with or without endocrine therapy HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting
 - b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Negative pregnancy test in a woman of child bearing potential
 - b. Eastern Cooperative Oncology Group performance status of 0-1
 5. When using Tukysa (tucatinib) and capecitabine combination, individual does not have severe renal impairment (CLcr < 30 mL/min)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Tukysa (tucatinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual's condition responded while on therapy
 - a. Response is defined as:
 - i. No evidence of disease progression
 - ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
 3. Dose is at least 150 mg twice a day
 4. Used combination with trastuzumab and capecitabine



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5. When using Tukysa (tucatinib) and capecitabine combination, individual does not have severe renal impairment (CLcr < 30 mL/min)
6. Individual has been adherent with the medication
7. Individual has not developed any significant adverse drug effects that may exclude continued use
 - a. Significant adverse effect such as:
 - i. Life threatening diarrhea despite use of anti-diarrheal agents
 - ii. Life threatening hepatotoxicity
 - iii. Other life threatening adverse effect
8. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
1. **Off-Label Use of a Non-Cancer Medications**
 2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Tukysa (tucatinib) is indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

Tucatinib inhibits phosphorylation of HER2 and HER3, resulting in inhibition of downstream MAPK and AKT signaling and cell proliferation, and showed anti-tumor activity in HER2 expressing tumor cells. In vivo, tucatinib inhibited the growth of HER2 expressing tumors. The combination of tucatinib and trastuzumab showed increased anti-tumor activity in vitro and in vivo compared to either drug alone.



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Definitions:

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982

Resources:

Tukysa (tucatinib) product information, revised by Seattle Genetics, Inc. 04-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on March 22, 2021.

Ma CX, Sparano JA. Treatment approach to metastatic hormone-receptor positive, HER2-negative breast cancer: Endocrine therapy and targeted agents. In: UpToDate, Hayes DF, Vora SR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed on March 17, 2021.

Gradishar WJ, Ruddy KJ. Breast cancer in men. In: UpToDate, Chagpar AB, Hayes DF, Vora SR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed on March 17, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 2.2021 – Updated March 12, 2021. Available at <https://www.nccn.org>. Accessed on March 16, 2021.

National Comprehensive Cancer Network (NCCN) Compendium: Tukysa. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021(c); Available at: <http://www.nccn.org>. Accessed on March 22, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.