PHARMACY COVERAGE GUIDELINE

TRUQAP™ (capivasertib) oral
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Truqap (capivasertib) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** 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. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Individual with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more *PIK3CA/AKT1/PTEN*-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy

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. **For premenopausal and perimenopausal woman**: A luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards is administered

5. **For a male**: Consider administering a LHRH agonist according to current clinical practice standards

6. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
   a. Individual is HR-positive, HER2-negative advanced or metastatic breast cancer with the presence of one or more of the following genetic alterations in tumor tissue: *PIK3CA/AKT1/PTEN*
   b. Eastern Co-operative Oncology Group (ECOG) status 0-1
   c. Blood glucose level, optimize blood glucose level if abnormal
   d. Hemoglobin A1C
   e. Documented negative pregnancy test in a woman of childbearing potential

7. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. Individual is not currently taking any other drugs which may result in a significant drug interaction such as use of moderate and strong CYP3A inducers (e.g., armodafinil, bexarotene, bosentan, dabrafenib, dexamethasone, rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, others)

9. Individual does not have a creatinine clearance of less than 30 mL/min

10. Individual does not have severe hepatic impairment (bilirubin > 3x upper limit of normal and any aspartate aminotransferase)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Truqap (capivasertib) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

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 has responded while on therapy with response defined as the following:
   a. There is no evidence of disease progression
   b. There is no evidence of unacceptable drug toxicity

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use such as:
    a. Severe or life-threatening hyperglycemia associated with ketoacidosis
    b. Severe or life-threatening diarrhea with dehydration
    c. Severe or life-threatening cutaneous reaction such as erythema multiforme (EM), palmar-plantar erythrodysesthesia, and drug reaction with eosinophilia and systemic symptoms (DRESS)
    d. Other adverse reaction(s) that are life-threatening

6. Individual is not currently taking any other drugs which may result in a significant drug interaction such as use of moderate and strong CYP3A inducers (e.g., armodafinil, bexarotene, bosentan, dabrafenib, dexamethasone, rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, others)

7. Individual does not have a creatinine clearance of less than 30 mL/min

8. Individual does not have severe hepatic impairment (bilirubin > 3x upper limit of normal and any aspartate aminotransferase)

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 Non-Cancer Medications**

    2. **Off-Label Use of Cancer Medications**

Description:

Truqap (capivasertib) is a kinase inhibitor indicated, in combination with fulvestrant for the treatment of adult individuals with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

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NCCN Guidelines Version 6.2024 – Updated November 11, 2024: Invasive Breast Cancer					
Targeted Therapies & Associated Biomarker Testing for Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease					
Biomarkers Associated with FDA-Approved Therapies					
Breast Cancer Subtype	**Biomarker**	**Detection**	**FDA-Approved Agents**	**NCCN Category of Evidence**	**NCCN Category of Preference**
HR+/ HER2-	*PIK3CA* activating mutation	NGS, PCR (tumor tissue or blood)	Itovebi (navolisib) + Ibrance (palbociclib) + fulvestrant [aa]	Category 1	Useful in certain circumstances first-line therapy
HR+/ HER2-	*PIK3CA* activating mutation	NGS, PCR (tumor tissue or blood)	Piqray (alpelisib) + fulvestrant	Category 1	Preferred second or subsequent-line therapy
HR+/ HER2- [y]	*PIK3CA* or *AKT1* activating mutations or *PTEN* alterations	NGS, PCR (tumor tissue or blood)	Truqap (capivasertib) + fulvestrant [y]	Category 1	Preferred second or subsequent-line therapy in select patients [y]
HR+/ HER2- [z]	*ESR1* mutation	NGS, PCR (Blood preferred)	Orserdu (elacestrant) [z]	Category 2A	Other recommended regimen
aa - Consider for disease progression on adjuvant endocrine therapy or relapse within 12 months of adjuvant endocrine therapy completion y - In adult patients with *PIK3CA* or *AKT1* activating mutations, or for *PTEN* alterations after disease progression or recurrence after ≥1 prior lines of endocrine therapy, including one line containing a CDK4/6 inhibitor z - For postmenopausal or premenopausal patients receiving ovarian ablation or suppression or adult males with ER-positive, HER2-negative, ESR1-mutated disease after progression on one or two prior lines of endocrine therapy, including one line containing a CDK4/6 inhibitor. Assess for ESR1 mutations at progression following prior lines of endocrine therapy NGS - Next-generation sequencing PCR - Polymerase chain reaction					

Endocrine therapies:

- anastrozole, exemestane, letrozole, tamoxifen

CDK4/6 inhibitor therapies:

- Ibrance (palbociclib), Verzenio (abemaciclib), Kisqali (ribociclib), Kisqali Femara Co-Pack (ribociclib/ letrozole)

Resources:

Truqap (capivasertib) product information, revised by AstraZeneca Pharmaceuticals LP 09-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 10, 2024.

Ma CX, Sparano JA. Treatment for hormone receptor-positive, HER2-negative advanced breast cancer. In: UpToDate, Burnstein HJ, Vora SR. Editor(s) (Ed), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through December 2024. Topic last updated January 08, 2025. Accessed January 29, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 6.2024 –Updated November 11, 2024. Available at https://www.nccn.org. Accessed January 29, 2025.

Turner NC, Oliveira M, Howell SJ, et al.: Capivasertib in hormone receptor-positive advanced breast cancer. N Engl J Med 2023;388:2058-70. DOI: 10.1056/NEJMoa2214131. Accessed December 05, 2023. Re-evaluated January 29, 2025.

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

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

ORIGINAL EFFECTIVE DATE: 02/15/2024 | ARCHIVE DATE: | LAST REVIEW DATE: 02/20/2025 | LAST CRITERIA REVISION DATE: