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/or 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.

Medical Necessity Requirements for TRUQAP (capivasertib)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Oncologist or in consultation with an Oncologist

Indication
- Used in combination with fulvestrant to treat hormone receptor positive, human epidermal growth factor receptor 2 negative, locally advanced or metastatic breast cancer with *PIK3CA*, *AKT1*, or *PTEN* alterations after progression on one endocrine based therapy or recurrence within 12 months of completing adjuvant therapy

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- Other oncologic direct treatment use listed in National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Confirmation of hormone receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer with at least one tumor tissue alteration in *PIK3CA*, *AKT1*, or *PTEN*
- Eastern Cooperative Oncology Group status of 0 or 1
- Blood glucose level (optimize if abnormal)
- Hemoglobin A1C
- Documented negative pregnancy test in a woman of childbearing potential

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (If available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- No concomitant use of moderate and strong CYP3A inducers (e.g., armodafinil, bexarotene, bosentan, dabrafenib, dexamethasone, rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin)

Additional Requirements
- Does not have creatinine clearance less than 30 mL per minute
- Does not have severe hepatic impairment (bilirubin greater than 3 times upper limit of normal and any aspartate aminotransferase)
- **For premenopausal and perimenopausal woman**: A luteinizing hormone releasing hormone (LHRH) agonist according to current clinical practice standards is administered
- **For a male**: Consider administering a LHRH agonist according to current clinical practice standards

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results (Eastern Cooperative Oncology Group status, blood glucose level, hemoglobin A1C, pregnancy test)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

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Prescriber Qualifications

- Continues to be seen by a physician specializing in or is in consultation with an Oncologist

Clinical Response

- No evidence of disease progression
- No evidence of unacceptable drug toxicity

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No development of **ANY** of the following:
  - Severe or life threatening hyperglycemia associated with ketoacidosis
  - Severe or life threatening diarrhea with dehydration
  - Severe or life threatening cutaneous reaction such as erythema multiforme, palmar plantar erythrodysesthesia, drug reaction with eosinophilia and systemic symptoms
  - Other life threatening adverse reactions
- No concomitant use of moderate and strong CYP3A inducers (e.g., armodafinil, bexarotene, bosentan, dabrafenib, dexamethasone, rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin)

Additional Requirements

- Does not have creatinine clearance less than 30 mL per minute
- Does not have severe hepatic impairment (bilirubin greater than 3 times upper limit of normal and any aspartate aminotransferase)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use (creatinine clearance, hepatic function, blood glucose, hemoglobin A1C)

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

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

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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

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 02-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 24, 2025.

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 October 2025. Topic last updated October 22, 2025. Accessed November 14, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 5.2025 – Updated October 16, 2025. Available at https://www.nccn.org. Accessed November 14, 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 November 14, 2025.

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.

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