



Commercial PA Criteria
Effective: December 18, 2023

Prior Authorization: Truqap (capivasertib)

Products Affected: Truqap (capivasertib) oral tablets

Medication Description: Capivasertib is an inhibitor of all 3 isoforms of serine/threonine kinase AKT (AKT1, AKT2 and AKT3) and inhibits phosphorylation of downstream AKT substrates. AKT activation in tumors is a result of activation of upstream signaling pathways, mutations in AKT1, loss of phosphatase and tensin homolog (PTEN) function and mutations in the catalytic subunit alpha of phosphatidylinositol 3-kinase (PIK3CA)
Truqap is a first-in-class oral adenosine triphosphate (ATP)-competitive inhibitor of all three AKT isoforms (AKT1/2/3).

Covered Uses: TRUQAP, in combination with fulvestrant, is indicated for the treatment of adult patients 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-alteration 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.

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Previous Therapies tried and failed

Prescriber Restriction: Medication must be prescribed by, or in consultation with, an oncologist

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Breast Cancer.** Approve if the patient meets the following:
 - A. Patient has locally advanced or metastatic disease; **AND**
 - B. Patient has hormone receptor-positive (HR+) disease; **AND**
 - C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
 - D. Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration; **AND**
 - E. Patient meets one of the following (i or ii):
 - i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting; **OR**

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Note: Examples of endocrine-based therapy include anastrozole, exemestane, and letrozole.

- ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.

References:

1. Product Information: TRUQAP™ oral tablets, capivasertib oral tablets. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2023

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/18/2023