Truqap® capivasertib 160 mg • 200 mg tablets | AstraZeneca Access 360™

# Coding Resource

## Indications and Usage

- 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-authorized 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
- TRUQAP in combination with abiraterone and prednisone is indicated for the treatment of adult patients with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.

## National Drug Code (NDC)[1]

### 10-digit NDC

| Dosage | Code |
|---|---|
| 160 mg Blister Pack of 4 x 16 tablets | 0310-9500-02 |
| 200 mg Bottle of 64 tablets | 0310-9501-01 |
| 200 mg Blister Pack of 4 x 16 tablets | 0310-9501-02 |
| 200 mg Blister Pack of 2 x 16 tablets | 0310-9501-04 |

### 11-digit NDC

| Dosage | Code |
|---|---|
| 160 mg Blister Pack of 4 x 16 tablets | 00310-9500-02 |
| 200 mg Bottle of 64 tablets | 00310-9501-01 |
| 200 mg Blister Pack of 4 x 16 tablets | 00310-9501-02 |
| 200 mg Blister Pack of 2 x 16 tablets | 00310-9501-04 |

## Diagnosis Codes[2]

| ICD-10-CM | Description |
|---|---|
| **PRIMARY BREAST CANCER SITE** | |
| C50.011 | Malignant neoplasm of nipple and areola, right female breast |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast |
| C50.121 | Malignant neoplasm of central portion of right male breast |
| C50.122 | Malignant neoplasm of central portion of left male breast |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast |

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

**Please see Important Safety Information on pages 5-6 and complete Prescribing Information, including Patient Information for TRUQAP.**

# Coding Resource

## Diagnosis Codes[2] (cont'd)

| ICD-10-CM | Description |
|---|---|
| **PRIMARY BREAST CANCER SITE** (cont'd) | |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast |
| C50.621 | Malignant neoplasm of axillary tail of right male breast |
| C50.622 | Malignant neoplasm of axillary tail of left male breast |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast |
| C50.822 | Malignant neoplasm of overlapping sites of left male breast |

# Coding Resource

## Diagnosis Codes[2] (cont'd)

| ICD-10-CM | Description |
|---|---|
| **PRIMARY BREAST CANCER SITE** (cont'd) | |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |
| C50.912 | Malignant neoplasm of unspecified site of left female breast |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast |
| C50.921 | Malignant neoplasm of unspecified site of right male breast |
| C50.922 | Malignant neoplasm of unspecified site of left male breast |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast |
| **PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST** | |
| Z85.3 | Personal history of malignant neoplasm of breast |
| **ESTROGEN RECEPTOR STATUS** | |
| Z17.0 | Estrogen receptor positive status [ER+] |
| Z17.1 | Estrogen receptor negative status [ER-] |
| **METASTASIS TO BONE AND BONE MARROW** | |
| C79.51 | Secondary malignant neoplasm of bone |
| C79.52 | Secondary malignant neoplasm of bone marrow |
| **METASTASIS TO LUNG AND PLEURA** | |
| C78.00 | Secondary malignant neoplasm of unspecified lung |
| C78.01 | Secondary malignant neoplasm of right lung |
| C78.02 | Secondary malignant neoplasm of left lung |
| C78.1 | Secondary malignant neoplasm of mediastinum |
| C78.2 | Secondary malignant neoplasm of pleura |
| C78.30 | Secondary malignant neoplasm of unspecified respiratory organ |
| C78.39 | Secondary malignant neoplasm of other respiratory organs |
| **METASTASIS TO BRAIN** | |
| C79.31 | Secondary malignant neoplasm of brain |
| C79.32 | Secondary malignant neoplasm of cerebral meninges |
| **METASTASIS TO BRAIN** | |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct |

# Coding Resource

## Diagnosis Codes[2] (cont'd)

| ICD-10-CM | Description |
|---|---|
| **PRIMARY PROSTATE CANCER SITE** | |
| C61 | Malignant neoplasm of prostate |
| **PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE** | |
| Z85.46 | Personal history of malignant neoplasm of prostate |
| **METASTASIS TO BONE AND BONE MARROW** | |
| C79.51 | Secondary malignant neoplasm of bone |
| C79.52 | Secondary malignant neoplasm of bone marrow |
| **METASTASIS TO LYMPH NODES** | |
| C77.1 | Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes |
| C77.2 | Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes |
| C77.3 | Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes |
| C77.4 | Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes |
| C77.5 | Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes |
| C77.8 | Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions |
| C77.9 | Secondary and unspecified malignant neoplasm of lymph node, unspecified |
| **GENETIC SUSCEPTIBILITY** | |
| Z15.03 | Genetic susceptibility to malignant neoplasm of prostate |
| **HORMONE SENSITIVE MALIGNANCY STATUS** | |
| Z19.1 | Hormone sensitive malignancy status |
| **PERSONAL HISTORY** | |
| Z92.29 | Personal history of other drug therapy |

# IMPORTANT SAFETY INFORMATION ABOUT TRUQAP® (capivasertib) tablets

TRUQAP is contraindicated in patients with severe hypersensitivity to TRUQAP or any of its components.

**Hyperglycemia**

TRUQAP can cause severe hyperglycemia, including diabetic ketoacidosis and fatal outcomes

*Metastatic HR-Positive, HER2-Negative Breast Cancer*

- In CAPItello-291, increased fasting glucose (FG) from baseline occurred in 37% of patients treated with TRUQAP, including 11% of patients with Grade 2 (FG >160 to 250 mg/dL), 2% with Grade 3 (FG >250 to 500 mg/dL), and 1.1% with Grade 4 (FG >500 mg/dL) events
- The median time to first occurrence of hyperglycemia was 15 days (range: 1 to 367). Dose reduction for hyperglycemia was required in 0.6% of patients and permanent discontinuation was required in 0.6% of patients. Diabetic metabolic decompensation occurred in 0.6% of patients, including diabetic ketoacidosis in 0.3%
- In the study, 12% (43/355) of patients who received TRUQAP had an anti-hyperglycemic medication regimen either initiated or changed, including treatment with insulin in 4.8% (17/355) of patients

*PTEN-Deficient Metastatic Androgen Pathway Modulation-Naïve or -Sensitive Prostate Cancer*

- In CAPItello-281, increased fasting glucose (FG) from baseline occurred in 69% of patients treated with TRUQAP, including 25% of patients with Grade 2 (FG >160 to 250 mg/dL), 12% with Grade 3 (FG >250 to 500 mg/dL), and 1.2% of patients with Grade 4 (FG >500 mg/dL) events
- The median time to first occurrence of hyperglycemia was 71 days (range: 1 to 1454). Dose reduction for hyperglycemia was required in 8.7% of patients and permanent discontinuation was required in 2.4% of patients. Diabetic ketoacidosis occurred in 1.2% of patients
- In the study, 41% (204/503) of patients who received TRUQAP had an anti-hyperglycemic medication regimen either initiated or changed, including treatment with insulin in 16% (81/503) of patients

The safety of TRUQAP has not been established in patients with Type 1 diabetes or Type 2 diabetes that is uncontrolled or requiring insulin at baseline as these patients were excluded from clinical studies. Before initiating treatment with TRUQAP, test fasting glucose levels (FPG or FBG), HbA1C levels, and optimize fasting glucose. After initiating treatment with TRUQAP, monitor or self-monitor FG levels on Day 3 or 4 of the dosing week during weeks 1, 2, 4, 6, and 8; then monthly while on treatment with TRUQAP; and as clinically indicated. Monitor HbA1C levels every 3 months during treatment with TRUQAP and as clinically indicated. Patients with a history of well-controlled Type 2 diabetes mellitus may require intensified anti-hyperglycemic treatment and close monitoring of FG levels.

For patients who experience hyperglycemia during treatment with TRUQAP, monitor FG at least twice weekly, on days on and off TRUQAP, until FG decreases to baseline levels. During treatment with anti-diabetic medications, monitor FG at least once a week for 2 months, followed by once every 2 weeks, or as clinically indicated. Consider consultation with a healthcare practitioner with expertise in the treatment of hyperglycemia and initiation of FG monitoring at home for patients who have risk factors for hyperglycemia or who experience hyperglycemia. Advise patients on the signs and symptoms of hyperglycemia and counsel patients on lifestyle changes.

Withhold TRUQAP immediately when ketoacidosis is suspected. If ketoacidosis is confirmed, permanently discontinue TRUQAP. Withhold TRUQAP in clinical situations known to increase the risk of severe hyperglycemia or ketoacidosis (eg, suspected serious infection or acute illness). Based on the severity of hyperglycemia, withhold, reduce dose, or permanently discontinue TRUQAP.

**Diarrhea**

TRUQAP can cause severe diarrhea associated with dehydration

*Metastatic HR-Positive, HER2-Negative Breast Cancer*

- In CAPItello-291, diarrhea occurred in 72% of patients. Grade 3 or 4 diarrhea occurred in 9% of patients
- The median time to first occurrence was 8 days (range: 1 to 519). In the study, dose reductions were required in 8% of patients, and 2% of patients permanently discontinued TRUQAP due to diarrhea. In patients with Grade ≥2 diarrhea (n=93) with at least 1 grade improvement (n=89), median time to improvement from the first event was 4 days (range: 1 to 154)
- In the 257 patients with diarrhea, 59% required anti-diarrheal medications to manage symptoms

*PTEN-Deficient Metastatic Androgen Pathway Modulation-Naïve or -Sensitive Prostate Cancer*

- In CAPItello-281, diarrhea of any grade occurred in 264 (52%) patients. Grade 3 occurred in 31 (6%) patients and Grade 4 occurred in 1 (0.2%) patient
- The median time to first occurrence was 12 days (range: 3 to 48). In the study, dose reductions were required in 26 (5%) patients and 6 (1.2%) patients discontinued TRUQAP due to diarrhea
- In the 264 patients with diarrhea, anti-diarrheal medication was required in 64% (170/264) of patients to manage diarrhea symptoms

Monitor patients for signs and symptoms of diarrhea. Advise patients to increase oral fluids and start anti-diarrheal treatment at the first sign of diarrhea while taking TRUQAP. Withhold, reduce dose, or permanently discontinue TRUQAP based on severity.

**Cutaneous Adverse Reactions**

TRUQAP can cause cutaneous adverse reactions, which can be severe, including erythema multiforme (EM), palmar-plantar erythrodysesthesia (PPE), and drug reaction with eosinophilia and systemic symptoms (DRESS).

*Metastatic HR-Positive, HER2-Negative Breast Cancer*

- In CAPItello-291, cutaneous adverse reactions occurred in 58% of patients. Grade 3 or 4 cutaneous adverse reactions occurred in 17% of patients receiving TRUQAP. EM occurred in 1.7% of patients, and DRESS occurred in 0.3% of patients
- The median time to onset of cutaneous adverse reactions was 13 days (range: 1 to 575 days). Dose reduction was required in 7% of patients and 7% of patients permanently discontinued TRUQAP due to cutaneous adverse reactions
- Among the 204 patients with cutaneous adverse reactions, 44% (90/204) required corticosteroid treatment. Of these, 37% (76/204) were treated with topical corticosteroids and 19% (39/204) with systemic corticosteroids. In patients with Grade ≥2 cutaneous adverse reaction (n= 116) with at least 1 grade improvement (n=104), median time to improvement from the first event was 12 days (range: 2 to 544)

# IMPORTANT SAFETY INFORMATION ABOUT TRUQAP® (capivasertib) tablets (cont'd)

*PTEN-Deficient Metastatic Androgen Pathway Modulation-Naïve or -Sensitive Prostate Cancer*

- In CAPItello-281, cutaneous adverse reactions occurred in 53% of patients. Grade 3 cutaneous adverse reactions occurred in 84 (17%) patients and Grade 4 occurred in 1 (0.2%) patients
- The median time to onset of rash was 13 days (range: 11 to 63 days). In the study, dose reduction was required in 58 (12%) patients and 38 (8%) patients discontinued TRUQAP due to rash
- Among the 265 patients with cutaneous adverse reactions, 80% (212/265) required treatment and 91% (242/265) recovered in the study. Of these, 54% (115/212) were treated with topical corticosteroids and 25% (54/212) with systemic corticosteroids

Monitor patients for signs and symptoms of cutaneous adverse reactions. Early consultation with a dermatologist is recommended. Withhold, reduce dose, or permanently discontinue TRUQAP based on severity.

**Embryo-Fetal Toxicity**

Based on findings from animals and mechanism of action, TRUQAP can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRUQAP and for 1 month after the last dose.

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRUQAP and for 4 months after the last dose.

TRUQAP is used in combination with fulvestrant or abiraterone. Refer to the full Prescribing Information of fulvestrant or abiraterone for pregnancy and contraception information.

**ADVERSE REACTIONS**

*Metastatic HR-Positive, HER2-Negative Breast Cancer*

- Among the 355 patients who received TRUQAP in CAPItello-291, the most common (≥20%) adverse reactions, including laboratory abnormalities, were diarrhea (72%), cutaneous adverse reactions (58%), increased random glucose (57%), decreased lymphocytes (47%), decreased hemoglobin (45%), increased fasting glucose (37%), nausea and fatigue (35% each), decreased leukocytes (32%), increased triglycerides (27%), decreased neutrophils (23%), increased creatinine (22%), vomiting (21%), and stomatitis (20%)
- In the 155 patients with PIK3CA/AKT1/PTEN alterations treated with TRUQAP + fulvestrant, dose reductions due to adverse reactions were reported in 21% of patients. Permanent TRUQAP discontinuation due to an adverse reaction occurred in 10% of patients. Dose interruptions of TRUQAP occurred in 39% of patients

*PTEN-Deficient Metastatic Androgen Pathway Modulation-Naïve or -Sensitive Prostate Cancer*

- Among the 503 patients who received TRUQAP in CAPItello-281, the most common (≥20%) adverse reactions including laboratory abnormalities were increased fasting glucose (70%), decreased hemoglobin (61%), decreased lymphocytes (58%), cutaneous adverse reactions (53%), diarrhea (53%), decreased potassium (51%), increased creatinine (49%), increased non-fasting glucose (49%), increased alanine aminotransferase (38%), increased triglycerides (37%), increased aspartate aminotransferase (36%), decreased sodium (30%), and fatigue (26%)
- In the 503 patients treated with TRUQAP + abiraterone and prednisone, dose reductions due to adverse reactions were reported in 32% of patients. Permanent TRUQAP discontinuation due to an adverse reaction occurred in 20% of patients. Dose interruptions of TRUQAP occurred in 65% of patients

**DRUG INTERACTIONS**

**Strong CYP3A Inhibitors:** Avoid concomitant use with a strong CYP3A inhibitor. If concomitant use cannot be avoided, reduce the dose of TRUQAP and monitor patients for adverse reactions.

**Moderate CYP3A Inhibitors:** When concomitantly used with a moderate CYP3A inhibitor, reduce the dose of TRUQAP and monitor patients for adverse reactions.

**Strong or Moderate CYP3A Inducers:** Avoid concomitant use of TRUQAP with strong or moderate CYP3A inducers.

**Please see complete Prescribing Information, including Patient Information for TRUQAP.**

**You may report side effects related to AstraZeneca products.**

For more information, please contact AstraZeneca Access 360™ at **1-844-ASK-A360**, Monday through Friday, 8 AM - 6 PM ET.

**1-844-ASK-A360** (1-844-275-2360) **1-844-FAX-A360** (1-844-329-2360) **www.MyAccess360.com**

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**References: 1.** TRUQAP® (capivasertib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026. **2.** Centers for Medicare & Medicaid Services. ICD-10. Accessed March 5, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes

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