UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1429-2
Program	Prior Authorization/Notification
Medication	Truqap™ (capivasertib)
P&T Approval Date	1/2024, 1/2025
Effective Date	4/1/2025

1. Background:

Truqap (capivasertib) is a kinase inhibitor indicated, in combination with fulvestrant, 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-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.

2. Coverage Criteria [a]:

A. Patients less than 19 years of age

1. **Truqap** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Breast Cancer

1. **Initial Authorization**

   a. **Truqap** will be approved based on **all** of the following criteria:

      (1) Diagnosis of breast cancer

      -AND-

      (2) **One** of the following:

         (a) Locally advanced
         (b) Recurrent unresectable (local or regional)
         (c) Metastatic

      -AND-

      (3) Disease is hormone receptor (HR)-positive

      -AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(5) Presence of one or more PIK3CA/AKT1/PTEN-alterations

-AND-

(6) **One** of the following:

(a) Has progressed on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen)
(b) Recurrence on or within 12 months of completing adjuvant therapy

-AND-

(7) Used in combination with fulvestrant

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Truqap** will be approved based on **both** of the following criteria:

(1) Patient does not show evidence of progressive disease while on Truqap therapy

-AND-

(2) Used in combination with fulvestrant

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

1. Truqap [package insert]. Wilmington, DE: Astra Zeneca; September 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 25, 2024.

Program	Prior Authorization/Notification - Truqap™ (capivasertib)
Change Control	
1/2024	New program
1/2025	Annual review. Added 'recurrent unresectable' to disease type of the clinical criteria. Added reference.