

DRUG POLICY

Truqap™ (capivasertib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Truqap is 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 phosphatidylinositol 3-kinase/serine/threonine kinase AKT1/phosphatase and tensin homolog (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

Compendial Use

Recurrent breast cancer

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Documentation of test confirming presence of at least one of the following alterations: PIK3CA, AKT1, or PTEN
2. Documentation of HR and HER2 status

Criteria for Initial Approval

Breast Cancer

Authorization of 12 months may be granted for treatment of HR-positive, HER2-negative, PIK3CA/AKT1/PTEN-mutated locally advanced, recurrent, or metastatic breast cancer when all of the following criteria are met:

1. The requested medication will be used in combination with fulvestrant
2. The member meets one of the following criteria:
 - A. The member had disease progression while on or after receiving at least one endocrine-based regimen including a cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor (e.g., palbociclib [Ibrance], ribociclib [Kisqali], abemaciclib [Verzenio]) in the metastatic setting, or
 - B. The member had disease recurrence while on or within 12 months of completing adjuvant therapy with an endocrine-based regimen

Continuation of Therapy

Breast Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Criteria for Initial Approval when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Truqap (capivasertib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Truqap (capivasertib) 160 mg tablet	64 tablets per 28 days	400 mg orally twice daily for four consecutive days, followed by 3 days off Dose adjustments due to adverse reactions: <ul style="list-style-type: none">• First reduction: 320 mg orally twice daily for four consecutive days, followed by 3 days off• Second reduction: 200 mg orally twice daily for four consecutive days, followed by 3 days off
Truqap (capivasertib) 200 mg tablet	64 tablets per 28 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Truqap [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.

POLICY HISTORY

Policy #: 05.05.32

Original Effective Date: April 17, 2024

Reviewed: August 2025

Revised: July 23, 2025

Current Effective Date: April 17, 2024