

Capivasertib (TRUQAP) Criteria for Use November 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to the item below is met, then the patient should NOT receive capivasertib.

- Uncontrolled hyperglycemia¹
- Chronic, uncontrolled diarrhea
- Severe renal impairment (CrCl 15-29 ml/min)
- Severe hepatic impairment (bilirubin > 3x upper limit of normal and any AST)
- Unmanageable drug-drug or drug-food interaction
- Pregnancy
- Lactating

¹ Patients with diabetes mellitus Type 1, Type 2 receiving insulin or HbA1C \geq 8% were excluded from CAPItello-291; additionally, there are published case reports of hyperglycemic events in the non-diabetic population; follow recommended glucose monitoring schedule.

Inclusion Criteria

All of the following criteria must be met.

- Locally advanced, unresectable or metastatic breast cancer
- Hormone receptor (HR)-positive, HER2-negative disease
- Activating PIK3CA or AKT1 mutations or PTEN gene alteration as detected by an approved test
- Progressive disease on or after an endocrine-based regimen

Additional Inclusion Criteria

All of the following criteria must be met.

- Care is provided by a VA/VA Community Care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0 – 1
- Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria *Select if applicable*

- For females who can become pregnant: Pregnancy must be excluded prior to receiving capivasertib.
- For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 4 months after the last dose.

Other Justification

- _____