

Specialty Guideline Management

Truqap

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Truqap	capivasertib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

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 Use²

Recurrent breast cancer

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

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

Coverage Criteria

Breast Cancer^{1,2}

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:

- The requested medication will be used in combination with fulvestrant
- The member meets one of the following criteria:
 - 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
 - The member had disease recurrence while on or within 12 months of completing adjuvant therapy with an endocrine-based regimen including a CDK4/6 inhibitor

Continuation of Therapy

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

References

1. Truqap [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 6, 2024.