

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, 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-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 Uses²

Breast cancer

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

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|---------------------|
| Reference number(s) |
| 6252-A |

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 Cancer¹⁻³

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

- Disease has alterations in at least one of the following: PIK3CA, AKT1, or PTEN
- The requested medication will be used in combination with fulvestrant
- The member had disease progression or recurrence after at least one prior line of endocrine therapy plus a cyclin-dependent kinase 4 and 6 (CDK 4/6) inhibitor (e.g., abemaciclib [Verzenio], palbociclib [Ibrance], ribociclib [Kisqali])

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; February 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 3, 2025.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 4, 2025.