BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

Truqap

Description

Truqap (capivasertib)

Background
Truqap (capivasertib) is an inhibitor of all 3 isoforms of serine/threonine kinase AKT (AKT1, AKT2 and AKT3) and inhibits phosphorylation of downstream AKT substrates. AKT activation in tumors is a result of activation of upstream signaling pathways, mutations in AKT1, loss of phosphatase and tensin homolog (PTEN) function and mutations in the catalytic subunit alpha of phosphatidylinositol 3-kinase (PIK3CA). In vitro, Truqap reduced growth of breast cancer cell lines including those with relevant PIK3CA or AKT1 mutations or PTEN alteration. In vivo, Truqap alone and in combination with fulvestrant inhibited tumor growth of mouse xenograft models including estrogen receptor positive breast cancer models with alterations in PIK3CA, AKT1, and PTEN (1).

Regulatory Status
FDA-approved indication: Truqap 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 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 (1).

Truqap has warnings regarding hyperglycemia, diarrhea, and cutaneous adverse reactions. Monitor for signs and symptoms as appropriate. Withhold, reduce, or permanently discontinue Truqap based on severity (1).

Truqap may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Truqap and for 1 month after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Truqap and for 4 months after the last dose (1).

The safety and effectiveness of Truqap in pediatric patients less than 18 years of age have not been established (1).

Related policies
Piqray

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Truqap may be considered **medically necessary** if the conditions indicated below are met.

Truqap may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced or metastatic breast cancer

AND ALL of the following:

1. Hormone receptor (HR)-positive
2. Human epidermal growth factor receptor 2 (HER2)-negative
3. One or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test
4. Used in combination with fulvestrant (Faslodex)

5. Patient must have **ONE** of the following:
    a. Disease progression on at least one endocrine-based regimen in the metastatic setting
    b. Recurrence on or within 12 months of completing adjuvant therapy
6. Prescriber agrees to monitor for elevated glucose and decrease the dose or discontinue therapy as required
7. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 1 month after the last dose
8. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced or metastatic breast cancer

AND ALL of the following:

1. Used in combination with fulvestrant (Faslodex)
2. **NO** disease progression or unacceptable toxicity
3. Prescriber agrees to monitor for elevated glucose and decrease the dose or discontinue therapy as required
4. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 1 month after the last dose
5. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 192 tablets per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Truqap (capivasertib) is a kinase inhibitor indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer. Truqap has warnings regarding hyperglycemia, diarrhea, cutaneous adverse reactions, and fetal harm. The safety and effectiveness of Truqap in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Truqap while maintaining optimal therapeutic outcomes.

References

1. Truqap [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. NCCN Drugs & Biologics Compendium® Capivasertib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.

Policy History

Date	Action
December 2023	Addition to PA
March 2024	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.