| Pharmacy Policy Bulletin: J-1358 Truqap (capivasertib) – Commercial and Healthcare Reform | |
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| **Number:** J-1358 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.):**<br>**1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization<br><br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-1358-002 | **Original Date:** 01/31/2024 |
| **Effective Date: 12/20/2024** | **Review Date:** 12/04/2024 |

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| **Drugs Product(s):** | • Truqap (capivasertib) |
| **FDA-Approved Indication(s):** | • 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 (*PIK3CA*)/protein kinase B (*AKT*)1/phosphatase and tensin homolog (*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. |

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| **Background:** | • Truqap is an inhibitor of all 3 isoforms of serine/threonine kinase AKT, inhibiting phosphorylation of downstream AKT substrates. AKT activation in tumors is a result of activation of upstream signaling pathways, mutations in *AKT1*, loss of PTEN function, and mutations in the catalytic subunit alpha of PIK3CA.<br>• The only other FDA-approved option for breast cancer with a *PIK3CA/AKT1/PTEN*-alteration is Piqray (alpelisib), which is specifically approved for PIK3CA-mutated advanced or metastatic HR-positive, HER2-negative breast cancer. Truqap is an AKT inhibitor while Piqray is a phosphatidylinositol-3-kinase (PI3K) inhibitor. Piqray and Truqap are both approved for adult patients. Truqap is approved following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy; Piqray is approved following progression on or after an endocrine-based regimen.<br>• Examples of endocrine therapy include tamoxifen or an aromatase inhibitor (e.g. anastrozole, letrozole, or exemestane). Patients in the clinical trial for Truqap were required to have experienced recurrence on or within 12 months of completing (neo)adjuvant treatment with an aromatase inhibitor.<br>• FoundationOne®CDx, a qualitative next-generation sequencing test, is to be used as a companion diagnostic for Truqap. The test is intended to provide tumor mutation profiling to be used by qualified health care professionals in |

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| | accordance with professional guidelines in oncology for patients with solid malignant neoplasm.<br>• Prescribing Considerations:<br>○ Truqap has warnings and precautions for hyperglycemia, diarrhea, cutaneous adverse reactions, and embryo-fetal toxicity |

## Approval Criteria

**I. Initial Authorization**

When a benefit, coverage of Truqap may be approved when all of the following criteria are met **(A. through F.)**:

**A.** The member is 18 years of age or older.

**B.** The member has a diagnosis of locally advanced or metastatic breast cancer (ICD-10: C50).

**C.** The member is using Truqap in combination with fulvestrant.

**D.** The member has tumor status of HR-positive, HER2-negative.

**E.** The member has one (1) of the following alterations as detected by an FDA-approved test **(1., 2., or 3.)**:

**1.** *PIK3CA*

**2.** *AKT1*

**3.** *PTEN*

**F.** The member meets one (1) of the following criteria **(1. or 2.)**:

**1.** The member has experienced disease progression on at least one (1) endocrine-based regimen in the metastatic setting.

**2.** The member has experienced recurrence on or within 12 months of completing adjuvant therapy.

**II. Reauthorization**

When a benefit, reauthorization of Truqap may be approved when the following criterion is met **(A.)**:

**A.** The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as either one (1) of the following **(1. or 2.)**:

**1.** Disease improvement

**2.** Delayed disease progression

**III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

**IV.** Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12-month authorization may be granted.

## Automatic Approval Criteria

None

**References:**


1. Truqap [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2023.
3. Piqray [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
4. National Comprehensive Cancer Network. NCCN Guidelines Version 5. 2024 Breast Cancer. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 4, 2024.



*Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.*

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