PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Truqap Prior Authorization Policy
- Truqap™ (capivasertib tablets – AstraZeneca)

REVIEW DATE: 07/10/2024

OVERVIEW

Truqap, a kinase inhibitor, is indicated in combination with fulvestrant for the treatment of 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*)/ serine/threonine protein kinase 1 (*AKT1*)/ 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 in adults.[1]

Guidelines

National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 4.2024 – July 3, 2024) state that for patients with HR+/HER2-negative tumors with *PIK3CA or AKT1* activating mutations or *PTEN* alterations, Truqap + fulvestrant is a "Preferred Regimen" for second or subsequent-line therapy in selected patients (category 1).[2] This would include adults with *PIK3CA/AKT1*activating mutations or *PTEN* alterations after disease progression or recurrence after one or more prior lines of endocrine therapy, including one line containing a cyclin-dependent kinase (CDK) 4/6 inhibitor. In this setting, for patients with PIK3CA-mutated tumors, Piqray® (alpelisib tablets) + fulvestrant is recommended (category 1). In the first-line setting for all patients, aromatase inhibitor or fulvestrant is recommended in combination with a CDK4/6 inhibitor (category 1 or category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Truqap. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Truqap is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Breast Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND
   - **C)** Patient has hormone receptor-positive (HR+) disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (*HER2*)-negative disease; AND
   - **E)** Patient has at least one phosphatidylinositol 3-kinase (*PIK3CA*), serine/threonine protein kinase (*AKT1*), or phosphatase and tensin homolog (*PTEN*)-alteration; AND
   - **F)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets BOTH of the following (a and b):

a) Patient has had progression with at least one endocrine-based regimen in the metastatic setting; AND
Note: Examples of endocrine-based therapy include anastrozole, exemestane, and letrozole.

b) Patient has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting; OR
Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets).

ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Truqap is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Truqap™ tablets [prescribing information]. Wilmington, DE: AstraZeneca; November 2023.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – July 3, 2023). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 5, 2024.