

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Truqap Prior Authorization Policy

- Truqap™ (capivasertib tablets – AstraZeneca)

REVIEW DATE: 11/29/2023; selected revision 01/03/2024

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 5.2023 – December 5, 2023) state that for patients with HR+/HER2-negative tumors with *PIK3CA/AKT1/PTEN*-activating mutations, 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/PTEN*-activating mutations 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 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 5.2023 –December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 3, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/29/2023
Selected Revision	Breast Cancer: For a patient who have has progression with at least one endocrine-based regimen in the metastatic setting, an additional requirement was added for the patient to have progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting. A note was added with examples of CDK4/6 inhibitor.	01/03/2024

