PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/10/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Truqap™ (capivasertib tablets – AstraZeneca)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Truqap™ (capivasertib tablets – AstraZeneca)**

is(are) considered experimental, investigational or unproven for ANY other use(s); 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/29/2023
Selected Revision	**Breast Cancer:** For a patient who has had 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
Annual Revision	No criteria changes.	07/10/2024