Evolent Clinical Guideline 3249 for Truqap™ (capivasertib)

Guideline Number:	Applicable Codes	
Evolent_CG_3249		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
December 2023	July 2026	July 2026

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STATEMENT

Purpose

To define and describe the accepted indications for Truqap (capivasertib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Breast Cancer

- Truqap (capivasertib), in combination with fulvestrant, may be used for the treatment of adult members with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer that have experienced disease progression on prior endocrine therapy, including a CDK4/6 inhibitor, AND the member's cancer is positive for one or more genomic aberrations involving AKT/PTEN.
- NOTE: The use of Truqap (capivarsitib) for metastatic ER/PR+, HER-2 negative metastatic breast cancer is not supported by Evolent policy for members whose cancer is positive for a PI3K mutation. The above policy position is based on the lack of Level 1 evidence (randomized clinical trial and or meta-analyses) to support superior outcomes with Truqap (capivasertib) in the population described above, compared to the Evolent supported alternative – Piqray (alpelisib).

Prostate Cancer

- Truqap (capivasertib) may be used in combination with Abirtega/Yonsa/Zytiga (abiraterone) and prednisone for the treatment of adult members with metastatic

androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Severe hypersensitivity to capivasertib or any component of the formulation.

EXCLUSION CRITERIA

- Disease progression while taking Truqap (capivasertib).
- For the treatment of breast cancer, members have not received prior endocrine based therapy.
- For the treatment of breast cancer, members have not received prior therapy with a CDK4/6 inhibitor (palbociclib, ribociclib, or abemaciclib).
- Dosing exceeds single dose limit of Truqap (capivasertib) 400 mg.
- Treatment with Truqap (capivasertib) exceeds the maximum limit of 64 (160 mg) and 64 (200 mg) tablets/month.
- Investigational use of Truqap (capivasertib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted

uses of drugs.

- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8999 - capivasertib

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
July 2026	• Added prostate cancer to indication section • Updated exclusion criteria • Updated references
December 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1494 Truqap (capivasertib) • Updated references
December 2024	• Added Evolent disclaimer language • Added Coding Information section with HCPCS code • Added maximum dosage form quantities to exclusion criteria

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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