Regimen Monograph

A - Regimen Name

CAPIFLVS Regimen

Capivasertib-Fulvestrant

Disease Site Breast

Intent Palliative

Regimen Category

Evidence-informed :

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

This **Regimen Abstract** is an **abbreviated** version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Rationale and Uses

Treatment of hormone receptor positive, HER2 negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations, following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Supplementary **fulvestrant**
Public Funding ODB - General Benefit (fulvestrant) (ODB Formulary)

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B - Drug Regimen

Cycle 1:

capivasertib	400 mg	PO	Twice daily; Days 1-4, 8-11, 15-18, 22-25 (4 days treatment, followed by 3 days off)

(This drug is not currently publicly funded for this regimen and intent)

fulvestrant	500 mg	IM	Days 1 and 15

Cycle 2 and beyond:

capivasertib	400 mg	PO	Twice daily; Days 1-4, 8-11, 15-18, 22-25 (4 days treatment, followed by 3 days off)

(This drug is not currently publicly funded for this regimen and intent)

fulvestrant	500 mg	IM	Day 1

In pre/peri-menopausal women, capivasertib plus fulvestrant should be combined with a luteinizing hormone releasing hormone (LHRH) agonist.

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

(For capivasertib, doses are given for 4 days each week, followed by 3 days off.)

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J - Administrative Information

Capivasertib: Outpatient prescription for home administration

Fulvestrant: Outpatient prescription; drug administration at Cancer Centre or physician's office

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K - References

Turner NC, Oliveira M, Howell SJ, et al. Capivasertib in Hormone Receptor-Positive Advanced Breast Cancer. N Engl J Med 2023 Jun 1;388(22):2058-70.

January 2025 new ST-QBP regimen

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

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Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate

that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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