Regimen Monograph

A - Regimen Name

CAPENERT Regimen

Capecitabine-Neratinib

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 For the treatment of patients with metastatic HER2-overexpressed/amplified breast cancer, who have received two or more prior anti-HER2-based regimens in the metastatic setting.

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B - Drug Regimen

neratinib	240 mg	PO	Daily
(This drug is not currently publicly funded for this regimen and intent)			
capecitabine	750 mg /m²	PO	BID Days 1 to 14; Q21 Days

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low – No routine prophylaxis; PRN recommended

Other Supportive Care:

- Initiate loperamide prophylaxis for diarrhea, starting with the first dose of neratinib. Primary prophylaxis with loperamide was mandatory for cycle 1 in the clinical trial. For cycles 2+, loperamide was used prn. Additional antidiarrheals may be required in patients with loperamide-refractory diarrhea.
- May also refer to the neratinib product monograph for loperamide titration to achieve 1-2 bowel movements a day.
- Topical emollients (e.g. hand creams, udder balm) may ameliorate the manifestations of hand-foot syndrome.

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Moy B, Oliveira M, Saura C, et al. Neratinib + capecitabine sustains health-related quality of life in patients with HER2-positive metastatic breast cancer and ≥ 2 prior HER2-directed regimens. Breast Cancer Res Treat. 2021 Jul;188(2):449-458.

Saura C, Oliveira M, Feng YH, et al. Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in HER2-Positive Metastatic Breast Cancer Previously Treated With ≥ 2 HER2-Directed Regimens: Phase III NALA Trial. J Clin Oncol. 2020 Sep 20;38(27):3138-3149.

April 2023 Updated DPD deficiency information in the Other Notes section

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L - Other Notes

DPD Deficiency Testing and Guidance:

Patients should be tested for DPD deficiency before starting treatment with capecitabine. Refer to the DPD Deficiency Guidance for Clinicians for more information.

In patients with unrecognized DPD deficiency, acute, life-threatening toxicity may occur; if acute grade 2-4 toxicity develops, treatment should be stopped immediately and permanent discontinuation considered based on clinical assessment of the toxicities.

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M - Disclaimer

Regimen Abstracts

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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.

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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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