Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | References | Other Notes | Disclaimer

A - Regimen Name

FEC+PEMB Regimen

Fluorouracil-EPIrubicin-Cyclophosphamide-Pembrolizumab

Disease Site Breast

Intent Neoadjuvant

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 neoadjuvant treatment of high-risk triple negative breast cancer (TNBC) in patients* without prior systemic therapy for non-metastatic TNBC

*with good performance status and no clinical contraindication for immunotherapy

Supplementary Public Funding	**pembrolizumab** New Drug Funding Program (Pembrolizumab - Previously Untreated High-Risk Early-Stage Triple Negative Breast Cancer) (NDFP Website)

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B - Drug Regimen

pembrolizumab[1,2]	2 mg /kg	IV (max 200 mg)	Day 1
fluorouracil	500 mg /m²	IV	Day 1
EPIrubicin	100 mg /m²	IV	Day 1
cyclophosphamide	500 mg /m²	IV	Day 1

[1]Dosing based on NDFP funding criteria. Refer to NDFP form for alternative pembrolizumab dosing schedule (4 mg/kg IV q6 weeks).

[2]Give pembrolizumab before chemotherapy when given on the same day.

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For 3 cycles, unless disease progression or unacceptable toxicity occurs

Followed by neoadjuvant DOCE+PEMB for 3 cycles

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D - Premedication and Supportive Measures

Antiemetic Regimen: High

Febrile Neutropenia Risk: Moderate

Also refer to CCO Antiemetic Recommendations.

Premedication for pembrolizumab (prophylaxis for infusion reactions):

- Routine pre-medication is not recommended.
- May consider antipyretic and H1-receptor antagonist in patients who experienced a grade 1-2 infusion reaction.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

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K - References

CADTH Reimbursement recommendation - Pembrolizumab: For the treatment of adult patients with high-risk early-stage triple negative breast cancer. September 2022.

Coudert B, Asselain B, Campone M, et al. Extended benefit from sequential administration of docetaxel after standard fluorouracil, epirubicin, and cyclophosphamide regimen for node-positive breast cancer: the 8-year follow-up results of the UNICANCER-PACS01 trial. Oncologist 2012;17(7):900-9.

Cyclophosphamide, epirubicin, fluorouracil and pembrolizumab drug monographs, Ontario Health (Cancer Care Ontario).

Mardarnas Y, Dent SF, Husain SF, et al. Real-world experience with adjuvant FEC-D chemotherapy in four Ontario regional cancer centres. Current Oncology 2011;18(3):119-25.

Roché H, Fumoleau P, Spielmann M, et al. Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: the FNCLCC PACS 01 Trial. JCO 2006; 24(36):5664-71.

Schmid J, Cortes L, Pusztai L, et al. Pembrolizumab for early triple-negative breast cancer. N Engl J

Med 2020;382:810-21.

Schmid P, Cortes J, Dent R, et al. Event-free survival with pembrolizumab in early triple-negative breast cancer. N Engl J Med 2022;386:556-67.

PEBC Advice Documents or Guidelines

- Optimal Systemic Therapy for Early Female Breast Cancer

September 2023 Updated the "Administrative Information" section with pharmacy and nursing workload.

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L - Other Notes

Patients should be tested for DPD deficiency before starting treatment with fluorouracil. 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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