

Regimen Monograph

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A - Regimen Name

DOCE+PEMB Regimen

DOCEtaxel-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)**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

After 3 cycles of FEC+PEMB:

pembrolizumab ^{1,2}	2 mg /kg	IV (max 200 mg)	Day 1
DOCEtaxel	100 mg /m ²	IV	Day 1

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

²Give 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

Refer to [PEMB](#) for the adjuvant pembrolizumab monotherapy phase.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

Febrile Neutropenia Risk: High

Consider G-CSF prophylaxis for patients at high risk of febrile neutropenia. See [G-CSF recommendations](#).

Also refer to [CCO Antiemetic Recommendations](#).

Premedication (prophylaxis for infusion reactions):

Pembrolizumab:

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

Docetaxel:

- Dexamethasone* 8 mg PO BID for 3 days, starting 1-day pre-infusion†

* Do not discontinue dexamethasone, even in the absence of an IR, due to the benefits on other adverse effects (e.g. pain and edema).

† Dexamethasone 10-20 mg IV can be given if patient forgot to take oral doses.

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J - Administrative Information

Approximate Patient Visit	2 hours
Pharmacy Workload (average time per visit)	34.686 minutes
Nursing Workload (average time per visit)	50.833 minutes

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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.

Docetaxel and pembrolizumab drug monographs, Ontario Health (Cancer Care Ontario).

Mardamas 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 nursing and pharmacy workload.

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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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