Regimen Monograph

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

A - Regimen Name

PACL+PEMB Regimen

PACLitaxel-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 4 cycles of AC+PEMB:

pembrolizumab[1,2]	2 mg /kg	IV (max 200 mg)	Day 1
PACLitaxel	175 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 4 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: Low

Also refer to CCO Antiemetic Recommendations.

Pre-medications (prophylaxis for infusion reaction):

Pembrolizumab:

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

Paclitaxel*:

- Dexamethasone 20 mg PO 12-and 6-hours OR Dexamethasone 20 mg IV 30 minutes pre-infusion†
- Diphenhydramine 25-50 mg IV/PO 30-60 minutes pre-infusion
- Ranitidine 50 mg IV OR Famotidine 20 mg IV 30-60 minutes pre-infusion

* Consider **discontinuing** pre-medications for paclitaxel if there was no IR in the first 2 doses.

† Oral and IV dexamethasone are both effective at reducing overall IR rates. Some evidence suggests that oral dexamethasone may be more effective for reducing severe reactions; however, adverse effects and compliance remain a concern.

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J - Administrative Information

Approximate Patient Visit	5 hours
Pharmacy Workload (average time per visit)	27.913 minutes
Nursing Workload (average time per visit)	49.833 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.

Henderson IC, Beryy D, Demetri G, Cirrincione C, et al. Improved outcomes from adding sequential Paclitaxel but not from escalating Doxorubicin dose in an adjuvant chemotherapy regimen for patients with node-positive primary breast cancer. J Clin Oncol, 2003 Mar15;21(6):976-83.

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

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.

Tan-Chiu E, Yothers G, Romond EH, et al. Assessment of cardiac dysfunction in a randomized trial comparing doxorubicin and cyclophosphamide followed by paclitaxel, with or without trastuzumab as adjuvant therapy in node-positive, Human Epidermal Growth Factor Receptor 2-overexpressing breast cancer: NSABP B-31. J Clin Oncol. 2005; 23(31): 7811-9.

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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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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