

Regimen Monograph

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A - Regimen Name

PACL(W)+PEMB Regimen

PACLitaxel (weekly)-Pembrolizumab

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 locally recurrent unresectable or metastatic triple negative breast cancer, with tumours expressing PD-L1 CPS ≥10.

If applicable, patients must have a minimum 6-month interval from completion of adjuvant treatment to recurrence of local or distant disease.

Patients must **NOT** have:

- unstable CNS metastases; OR
- received prior chemotherapy for metastatic or incurable locally advanced disease.

(Refer to NDFP form for details)

**Supplementary
Public Funding**

[pembrolizumab](#)

New Drug Funding Program (Pembrolizumab - Locally Recurrent Unresectable or Metastatic 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; Every 3 weeks
PACLitaxel	90 mg /m ²	IV	Days 1, 8, 15; Every 4 weeks

¹ Give pembrolizumab before chemotherapy when given on the same day.

² Dosing based on NDFP funding criteria. Alternative dosing schedule: pembrolizumab 4mg/kg (max 400mg) IV q6 weeks.

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C - Cycle Frequency

Pembrolizumab:

2 mg /kg dosing: REPEAT EVERY 3 WEEKS

4 mg /kg dosing: REPEAT EVERY 6 WEEKS

Until disease progression or unacceptable toxicity, up to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first.

Refer to NDFP form for details on pembrolizumab retreatment.

Paclitaxel: REPEAT EVERY 28 DAYS (3 weeks on, 1 week off)

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

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

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

Pre-medications (prophylaxis for 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.

Pembrolizumab:

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

Other Supportive Care:

- Avoid the use of corticosteroids or immunosuppressants before starting pembrolizumab treatment. Corticosteroids may be used as premedication (e.g. antiemetic) when given with chemotherapy.

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J - Administrative Information

Approximate Patient Visit	2.5 hours
Pharmacy Workload (average time per visit)	20.910 minutes
Nursing Workload (average time per visit)	39.833 minutes

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K - References

CADTH reimbursement recommendation: Pembrolizumab (In combination with chemotherapy, for the treatment of adult patients with locally recurrent unresectable or metastatic triple-negative breast cancer). January 2023.

Cortes J, Cescon DW, Rugo HS, et al. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer (KEYNOTE-355): a randomised, placebo-controlled, double-blind, phase 3 clinical trial. *Lancet*. 2020 Dec 5;396(10265):1817-28. doi: 10.1016/S0140-6736(20)32531-9.

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

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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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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