Regimen Monograph

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A - Regimen Name

CRBPPACL+PEMB Regimen

PACLitaxel-CARBOplatin-Pembrolizumab

Disease Site Lung

Non-Small Cell

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

Neoadjuvant treatment for previously untreated, resectable early-stage (II, IIIA, or IIIB (N2)) non-small cell lung cancer

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B - Drug Regimen

pembrolizumab ¹	200 mg	IV	Day 1
Dellibiolizullab			,

(This drug is not currently publicly funded for this regimen and intent)

PACLitaxel 175-200 mg /m² IV Day 1

CARBOplatin AUC 5-6* IV Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For 4 cycles unless disease progression or unacceptable toxicity occurs

Refer to PEMB for adjuvant treatment phase.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate + NK1 antagonist (Carboplatin AUC ≥ 5)

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 preinfusion[†]
- Diphenhydramine 25-50 mg IV/PO 30-60 minutes pre-infusion

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

^{*}Adjust Carboplatin dose to AUC target (using Calvert formula) as outlined in "Other Notes" section.

• Ranitidine 50 mg IV OR Famotidine 20 mg IV 30-60 minutes pre-infusion

Carboplatin:

- There is insufficient evidence that routine prophylaxis with pre-medications reduce infusion reaction (IR) rates.
- Corticosteroids and H1-receptor antagonists ± H2-receptor antagonists may reduce IR rates
 for some patients (e.g. gynecological patients with a platinum-free interval (PFI) > 12 months
 or a history of drug allergy who are receiving carboplatin starting from the 7th cycle) but no
 optimal pre-medication regimen has been established.

Other Supportive Care:

- Also refer to <u>CCO Antiemetic Recommendations</u>.
- Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.
- Avoid the use of corticosteroids or immunosuppressants before starting pembrolizumab treatment.

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J - Administrative Information

Approximate Patient Visit 5-6 hours

Pharmacy Workload (average time per visit) 39.6325 minutes

Nursing Workload (average time per visit) 69.833 minutes

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K - References

Carboplatin drug monograph. Ontario Health (Cancer Care Ontario).

Paclitaxel drug monograph. Ontario Health (Cancer Care Ontario).

Pembrolizumab drug monograph. Ontario Health (Cancer Care Ontario).

^{*}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

Spicer JD, Garassino MC, Wakelee H, et al. Neoadjuvant pembrolizumab plus chemotherapy followed by adjuvant pembrolizumab compared with neoadjuvant chemotherapy alone in patients with early-stage non-small-cell lung cancer (KEYNOTE-671): a randomised, double-blind, placebocontrolled, phase 3 trial. Lancet. 2024 Sep 28;404(10459):1240-52. doi: 10.1016/S0140-6736(24)01756-2.

May 2025 new ST-QBP regimen

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L - Other Notes

Calvert Formula

DOSE (mg) = target AUC X (GFR + 25)

- AUC = product of serum concentration (mg/mL) and time (min)
- GFR (glomerular filtration rate) expressed as measured Creatinine Clearance or estimated from Serum Creatinine (by Cockcroft and Gault method or Jelliffe method)

(Calvert AH, Newell DR, Gumbrell LA, et al, Carboplatin dosage: Prospective evaluation of a simple formula based on renal function. J Clin Oncol, 1989; 7: 1748-1756)

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M - Disclaimer

Regimen Abstracts

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Regimen Monographs

Refer to the <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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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