Regimen Monograph

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

A - Regimen Name

CRBPPACL Regimen

PACLitaxel-CARBOplatin

Disease Site	Skin - Melanoma
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	Treatment of patients with unresectable advanced or metastatic melanoma.

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B - Drug Regimen

PACLitaxel	175-200* mg /m²	IV	Day 1
CARBOplatin	AUC 5 to 6	IV	Day 1

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

*Some clinical trials reduced doses to paclitaxel 175mg/m^2 and carboplatin AUC 5 for cycles 5 on.

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity, usually up to 6 cycles due to cumulative carboplatin toxicity

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D - Premedication and Supportive Measures

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

Also refer to CCO Antiemetic Recommendations.

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.

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.

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J - Administrative Information

Approximate Patient Visit	5-6 hours
Pharmacy Workload (average time per visit)	30.383 minutes
Nursing Workload (average time per visit)	59.833 minutes

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K - References

Carboplatin and paclitaxel drug monographs, Cancer Care Ontario.

Flaherty KT, Lee SJ, Schuchter LM, et al. Final results of E2603: A double-blind, randomized phase III trial comparing carboplatin/paclitaxel with or without sorafenib in metastatic melanoma. J Clin Oncol 2010;28(15s):abstract 8511.

Hauschild A, Agarwala SS, Trefzer U, et al. Results of a Phase III, Randomized, placebo-controlled study of sorafenib in combination with carboplatin and paclitaxel as second-line treatment in patients with unresectable stage III or stage IV melanoma. J Clin Oncol 2009;27:2823-30.

Hodi S, Soiffer RJ, Clark J. Phase II study of paclitaxel and carboplatin for malignant melanoma. Am J Clin Oncol 2002;25(3):283–6.

Pflugfelder A, Eigentler TK, Keim U, et al. Effectiveness of carboplatin and paclitaxel as first- and second-line treatment in 61 patients with metastatic melanoma. PLoS One 2011;6(2):e16882.

Rao RD, Holtan SG, Ingle JN, et al. Combination of paclitaxel and carboplatin as second-line therapy for patients with metastatic melanoma. Cancer 2006;106:375–82.

August 2020 Updated infusion reaction information in Premedication and Supportive Measures

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

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