Regimen Monograph

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

A - Regimen Name

CRBPPACL(W) Regimen

CARBOplatin-PACLitaxel

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 treatment of high-risk triple negative breast cancer. (Note that the addition of carboplatin adds to the toxicity profile; the outcomes related to platinum use in the neoadjuvant setting have been variable.)

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B - Drug Regimen

<u>PACLitaxel</u>	80 mg /m²	IV	Days 1, 8, 15
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CARBOplatin AUC 4 to 6* IV Day 1

OR

CARBOplatin AUC 1.5* Days 1, 8, 15

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For 4 cycles, followed by AC(DD) x 4 cycles per usual standard

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D - Premedication and Supportive Measures

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

Moderate (Carboplatin AUC < 5)

Also refer to CCO Antiemetic Recommendations.

Pre-medications (prophylaxis for infusion reaction):

Paclitaxel*:

To be given 30-60 minutes prior to infusion:

- Dexamethasone 10 mg IV, starting in cycle 1
- Diphenhydramine 25-50 mg IV/PO
- Ranitidine 50 mg IV OR Famotidine 20 mg IV

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

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

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 2-2.5 hours

Pharmacy Workload (average time per visit) 22.569 minutes

Nursing Workload (average time per visit) 43.167 minutes

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K - References

Ando M, Yamauchi H, Aogi K et al. Randomized phase II study of weekly paclitaxel with and without carboplatin followed by cyclophosphamide/ epirubicin/5-fluorouracil as neoadjuvant chemotherapy for stage II/IIIA breast cancer without HER2 overexpression. Breast Cancer Res Treat 2014; 145(2): 401–409.

BC Cancer Protocol Summary for NEOAdjuvant Therapy for Triple Negative Breast Cancer Using Carboplatin and Weekly PACLitaxel Followed by DOXOrubicin and Cyclophosphamide. June 14, 2021.

Carboplatin and paclitaxel drug monographs, Cancer Care Ontario.

Loibl S, O'Shaughnessy J, Untch M et al. Addition of the PARP inhibitor veliparib plus carboplatin or carboplatin alone to standard neoadjuvant chemotherapy in triple-negative breast cancer (BrighTNess): a randomised, phase 3 trial. Lancet Oncol. 2018; 19(4): 497–509.

F Poggio, M Bruzzone, M Ceppi, et al. Platinum-based neoadjuvant chemotherapy in triple-negative

breast cancer: a systematic review and meta-analysis. Ann Oncol. 2018 Jul 1;29(7):1497-1508. doi: 10.1093/annonc/mdy127

Schmid J, Cortes L, Pusztai L, et al. Pembrolizumab for early triple-negative breast cancer. N Engl J Med 2020;382:810-21. DOI: 10.1056/NEJMoa1910549

Sikov WM, Berry DA, Perou CM et al. Impact of the addition of carboplatin and/or bevacizumab to neoadjuvant once-per-week paclitaxel followed by dose-dense doxorubicin and cyclophosphamide on pathologic complete response rates in stage II to III triple-negative breast cancer: cALGB 40603 (Alliance). J Clin Oncol 2015; 33(1): 13–21.

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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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undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

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.

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