**Regimen Monograph**



## A - Regimen Name

# CRBPDOCE+PEMB Regimen

**Carboplatin-Docetaxel-Pembrolizumab**

| | |
|---|---|
| **Disease Site** | Breast |
| **Intent** | Neoadjuvant |
| **Regimen Category** | **Evidence-informed :**<br><br>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.<br><br>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 triple negative breast cancer (TNBC) in patients without prior systemic chemotherapy or imunnotherapy for non-metastatic TNBC |
| **Supplementary Public Funding** | **pembrolizumab**<br>New Drug Funding Program (Pembrolizumab - Previously Untreated High-Risk |

Early-Stage Triple Negative Breast Cancer) (NDFP Website )

back to top

## B - Drug Regimen

| | | | |
|---|---|---|---|
| **pembrolizumab**[1,2] | 2 mg /kg | IV (max 200 mg) | Day 1 |
| **DOCEtaxel** | 75 mg /m² | IV | Day 1 |
| **CARBOplatin** | AUC 6* | 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.

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

back to top

## C - Cycle Frequency

**REPEAT EVERY 21 DAYS**

For 6 cycles unless disease progression or unacceptable toxicity occurs

back to top

## D - Premedication and Supportive Measures

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

- Also refer to CCO Antiemetic Recommendations.

**Febrile Neutropenia Risk:** High

Consider G-CSF prophylaxis for patients at high risk of febrile neutropenia. See G-CSF recommendations.

**Screen for hepatitis B virus in all cancer patients starting systemic treatment.** Refer to the hepatitis B virus screening and management guideline.

**Docetaxel Pre-medications (prophylaxis for infusion reaction):**

- Dexamethasone* 8 mg PO BID for 3 days, starting 1-day pre-infusion†

* Do not discontinue dexamethasone, even in the absence of an IR, due to the benefits on other adverse effects (e.g. pain and edema).

† Dexamethasone 10-20 mg IV can be given if patient forgot to take oral doses.

**Pembrolizumab Premedication (prophylaxis for infusion reactions):**

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

**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.

back to top

## J - Administrative Information

| | |
|---|---|
| Approximate Patient Visit | 3 hours |
| Pharmacy Workload (average time per visit) | 35.656 minutes |
| Nursing Workload (average time per visit) | 59.167 minutes |

back to top

## K - References

CADTH Reimbursement recommendation - Pembrolizumab: For the treatment of adult patients with high-risk early-stage triple negative breast cancer. September 2022.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.

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

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

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

Poggio F, Bruzzone M, Ceppi M, 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.

Sharma P, Stecklein SR, Yoder R, et al. Clinical and biomarker findings of neoadjuvant pembrolizumab and carboplatin plus docetaxel in triple-negative breast cancer: NeoPACT Phase 2 Clinical Trial. JAMA Oncol 2024 Feb 1;10(2):227-35.

Sharma P, Kimler BF, O'Dea A, et al. Randomized phase II trial of anthracycline-free and anthracycline-containing neoadjuvant carboplatin chemotherapy regimens in stage I-III triple-negative breast cancer (NeoSTOP). Clin Cancer Res 2021 Feb 15;27(4):975-82.

Sharma P, López-Tarruella S, García-Saenz JA, et al. Pathological response and survival in triple-negative breast cancer following neoadjuvant carboplatin plus docetaxel. Clin Cancer Res 2018 Dec 1;24(23):5820-9.

**May 2025** new ST-QBP regimen

back to top

## 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)

back to top

## M - Disclaimer

***Regimen Abstracts***

*A 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). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.*

*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.*

***Regimen Monographs***

*Refer to the New Drug Funding Program or Ontario Public Drug Programs 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.*

*The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of 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.*

*While care has been taken in the preparation of the information contained in the Formulary, such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability.*

*CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and*

*expenses) arising from such person's use of the information in the Formulary.*

back to top