Regimen Monograph

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

A - Regimen Name

CRBPGEMC(W)+PEMB Regimen

Gemcitabine-CARBOplatin-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)

back to top

B - Drug Regimen

pembrolizumab[1, 2]	2 mg /kg	IV (max 200 mg)	Day 1; every 3 weeks
gemcitabine	1000 mg /m²	IV	Days 1, 8
CARBOplatin	AUC 2	IV	Days 1, 8

[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.

back to top

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.

CRBPGEMC(W): REPEAT **EVERY 21 DAYS**

Until disease progression or unacceptable toxicity

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate (Carboplatin AUC < 5)

- Also refer to CCO Antiemetic Summary

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):

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.

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.

back to top

J - Administrative Information

Approximate Patient Visit	2.5 hours
Pharmacy Workload (average time per visit)	39.2 minutes

Nursing Workload (average time per visit) 51.667 minutes

back to top

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.

Carboplatin, gemcitabine, and pembrolizumab drug monographs. Ontario Health (Cancer Care Ontario).

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.

September 2023 Updated "Administrative Information Section" with nursing and pharmacy workload.

back to top

L - Other Notes

Calvert Formula: (area under the curve method)

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

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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.

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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back to top