Regimen Monograph

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

A - Regimen Name

CYCLDOCE+PEMB Regimen

Cyclophosphamide-DOCEtaxel-Pembrolizumab

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 neoadjuvant treatment of high-risk triple negative breast cancer (TNBC) in patients with good performance status and who:

- have not received prior systemic therapy for non-metastatic TNBC, and
- have contraindications to anthracyclines, and
- do not have clinical contraindication for immunotherapy

Supplementary Public Funding	**pembrolizumab** New Drug Funding Program (Pembrolizumab - Previously Untreated High-Risk Early-Stage Triple Negative Breast Cancer) (NDFP Website)

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B - Drug Regimen

pembrolizumab[1,2]	2 mg /kg	IV (max 200 mg)	Day 1
DOCEtaxel	75 mg /m²	IV	Day 1
cyclophosphamide	600 mg /m²	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.

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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 the adjuvant pembrolizumab monotherapy phase.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Febrile Neutropenia Risk: High

Primary prophylaxis with G-CSF is indicated for CYCLDOCE. Refer to the Febrile Neutropenia Guideline.

Also refer to CCO Antiemetic Recommendations.

Premedication (prophylaxis for infusion reactions):

Pembrolizumab:

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

Docetaxel:

- 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.

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

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J - Administrative Information

Approximate Patient Visit	2.5 hours
Pharmacy Workload (average time per visit)	47.335 minutes

Nursing Workload (average time per visit) 69.167 minutes

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K - References

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

Cyclophosphamide, docetaxel, and pembrolizumab drug monographs, Ontario Health (Cancer Care Ontario).

Jones S, Holmes FA, O'Shaughnessy JO, et al. Docetaxel with cyclophosphamide is associated with an overall survival benefit compared with doxorubicin and cyclophosphamide: 7-year follow-up of US oncology research trial 9735. JCO 2009; 27(8): 1177-83.

Jones SE, Mavin MA, Holmes FA et al. Phase III trial comparing doxorubicin plus cyclophosphamide with docetaxel plus cyclophosphamide as adjuvant therapy for operable breast cancer. JCO 2006; 24: 5381-7.

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

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.

PEBC Advice Documents or Guidelines

- Optimal Systemic Therapy for Early Female Breast Cancer

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

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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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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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