

Regimen Monograph

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A - Regimen Name

AC-PACL(DD)+PERT+TRAS Regimen

ADRIAMYCIN® (DOXOrubicin)-Cyclophosphamide then PACLitaxel (Dose Dense) and Pertuzumab, Trastuzumab

Disease Site Breast

Intent Curative
Adjuvant

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 in patients with early HER2-positive breast cancer who have a high risk of recurrence

Supplementary [trastuzumab](#)**Public Funding**

New Drug Funding Program (Trastuzumab (Biosimilar) - Adjuvant Treatment for Breast Cancer) ([NDFP Website](#))

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B - Drug Regimen

Note: Different trastuzumab products are **NOT INTERCHANGEABLE**.

AC: (x 4 cycles)

DOXOrubicin	60 mg /m ²	IV	Day 1
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cyclophosphamide	600 mg /m ²	IV	Day 1
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THEN

PACLITAXEL (Taxol®): (x 4 cycles)

PACLitaxel	175 mg /m ²	IV	Day 1
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Pertuzumab and Trastuzumab to be given every 21 Days for one year, starting concurrently with Paclitaxel:

PERTuzumab	840 mg	IV loading dose	Day 1
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(This drug is not currently publicly funded for this regimen and intent)

trastuzumab	8 mg /kg	IV loading dose	Day 1
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THEN,

PERTuzumab	420 mg	IV maintenance dose (Every 21 days)
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(This drug is not currently publicly funded for this regimen and intent)

trastuzumab	6 mg /kg	IV maintenance dose (Every 21 days)
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C - Cycle Frequency

REPEAT EVERY 14 DAYS: AC X 4 cycles then Paclitaxel (Taxol®) X 4 cycles.

Pertuzumab and trastuzumab to start concurrently with paclitaxel and continue q21 days .

Refer to [PERT+TRAS](#) for cycles after the chemotherapy is completed.

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D - Premedication and Supportive Measures

Antiemetic Regimen: High (AC)
Low (Paclitaxel)

Febrile Neutropenia Risk: High
Primary prophylaxis with G-CSF is indicated for AC-PACL(DD). Refer to the [Febrile Neutropenia Guideline](#).

Other Supportive Care:

Also refer to [CCO Antiemetic Recommendations](#).

Pre-medications* (prophylaxis for infusion reaction with 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.

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J - Administrative Information

Approximate Patient Visit	AC: 1 to 1.5 hours; Paclitaxel: 3 to 5 hours; PERT+TRAS: 3 hours (first cycle); 1-1.5 hours (subsequent cycles)
Pharmacy Workload (average time per visit)	29.158 minutes
Nursing Workload (average time per visit)	65.75 minutes

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Citron M, Berry D, Cirincione C, et al. Randomized trial of dose dense versus conventionally scheduled and sequential versus concurrent combination chemotherapy as postoperative adjuvant treatment of node-positive primary breast cancer: First Report of Intergroup Trial C9741/Cancer and Leukemia Group B trial 9741. J Clin Oncol; 2003 Apr 15. 21(8): 1431-1439.

doxorubicin, cyclophosphamide, paclitaxel drug monographs, Cancer Care Ontario.

von Minckwitz G, Proctor M, de Azambuja E, et al. Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer. N Engl J Med. 2017;377(2):122-131.

PEBC Advice Documents or Guidelines

- [Optimal Systemic Therapy for Early Female Breast Cancer](#)

September 2022 added statement on non-interchangeability of trastuzumab products

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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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