Regimen Monograph

 Regimen Name
 Drug Regimen
 Cycle Frequency
 Premedication and Supportive Measures
 Administrative Information

 References
 Other Notes
 Disclaimer

A - Regimen Name

AC-PACL(W)+PERT+TRAS Regimen

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

Disease Site Breast
Intent Curative
Adjuvant

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Regimen Evidence-informed :

Category

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 andTreatment in patients with early HER2-positive breast cancer who have a highUsesrisk of recurrence.

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Supplementary	<u>trastuzumab</u>
Public Funding	New Drug Funding Program (Trastuzumab (Biosimilar) - Adjuvant Treatment
	for Breast Cancer) (<u>NDFP Website</u>)

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B - Drug Regimen Note: Different trastuzumab products are NOT INTERCHANGEABLE. AC: (x 4 cycles) **DOXOrubicin** $60 \text{ mg}/\text{m}^2$ IV Day 1 cyclophosphamide $600 \text{ mg} / \text{m}^2$ IV Day 1 **Repeat Every 21 Days** THEN PACLITAXEL Weekly: (x 12 doses) PACLitaxel 80 mg /m² IV Day 1 **Repeat Every 7 Days** Pertuzumab and Trastuzumab to be given every 21 days for one year, starting concurrently with paclitaxel: PERTuzumab 840 mg IV loading dose Day 1 (This drug is not currently publicly funded for this regimen and intent) trastuzumab 8 mg /kg IV loading dose Day 1 THEN, PERTuzumab 420 mg IV maintenance dose (Every 21 days) (This drug is not currently publicly funded for this regimen and intent) 6 mg /kg IV maintenance dose (Every 21 days) trastuzumab

Alternative chemotherapy	schedule:			
AC: (x 4 cycles)				
DOXOrubicin	60 mg /m²	IV	Day 1	
<u>cyclophosphamide</u>	600 mg /m²	IV	Day 1	
Repeat Every 14 Days				
THEN				
PACLITAXEL Weekly: (x 12 doses)				
PACLitaxel	80 mg /m²	IV	Day 1	
Repeat Every 7 Days				
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C - Cycle Frequency

AC X 4 cycles then weekly Paclitaxel X 12 doses. Pertuzumab and trastuzumab to start concurrently with paclitaxel and continue q21 days

Refer to <u>PERT+TRAS</u> 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:	Low AC(Q3W)-PACL(W)		
	High AC(Q2W)-PACL(W): Use G-CSF prophylaxis for patients at high risk of febrile neutropenia. See <u>G-CSF recommendations</u> .		

Other Supportive Care:

Also refer to CCO Antiemetic Summary

Pre-medications^{*} (prophylaxis for infusion reaction):

To be given 30-60 minutes prior to paclitaxel infusion.

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

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

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J - Administrative Information

Approximate Patient Visit	AC: 1 to 1.5 hours; Cycles 5+: 2.5-3 hours; 2 hours (paclitaxel-ony days)
Pharmacy Workload (average time per visit)	23.31 minutes
Nursing Workload (average time per visit)	56.542 minutes

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K - References

Doxorubicin, cyclophosphamide, paclitaxel and trastuzumab drug monographs, Cancer Care Ontario.

Henderson IC, Berry D, Demetri G, Cirrincione C, et al. Improved outcomes from adding sequential paclitaxel but not from escalating doxorubicin dose in an adjuvant chemotherapy regimen for patients with node-positive primary breast cancer. J Clin Oncol 2003; 21(6): 976-83.

Romond EH, Perex EA, Bryant J, et al. Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. NEJM 2005; 353(16) 1673-84.

Sparano JA, Wang M, Martino S, et al. Weekly paclitaxel in the adjuvant treatment of breast cancer. NEJM 2008; 358(16): 1663-71.

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.

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PEBC Advice Documents or Guidelines

Optimal Systemic Therapy for Early Female Breast Cancer

September 2022 added statement on non-interchageability of trastuzumab products

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M - Disclaimer

Regimen Abstracts

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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 <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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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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

AC-PACL(W)+PERT+TRAS

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