Regimen Monograph

A - Regimen Name

PACL+PERTRAS(SC) Regimen

PACLitaxel-PERTuzumab (subcut)-Trastuzumab (subcut)

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	Treatment of patients with HER2 positive metastatic breast cancer

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B - Drug Regimen

Phesgo® (pertuzumab and trastuzumab combined subcut injection) is **not interchangeable** with other trastuzumab or pertuzumab formulations. Phesgo® has different dosage and administration instructions than IV pertuzumab, IV trastuzumab, and subcut trastuzumab when administered alone.

Cycle 1 - Trastuzumab and Pertuzumab Loading Dose:

PERTuzumab / trastuzumab (subcut)	1200 / 600 mg	Subcut	Day 1

(This drug is not currently publicly funded for this regimen and intent)

PACLitaxel	175 mg /m²	IV	Day 1

Cycle 2 and Onwards - Trastuzumab and Pertuzumab Maintenance Dose:

PERTuzumab / trastuzumab (subcut)	600 / 600 mg	Subcut	Day 1

(This drug is not currently publicly funded for this regimen and intent)

PACLitaxel	175 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity. If paclitaxel is discontinued (e.g., after 6-8 cycles or due to unmanageable toxicity), may continue treatment with PERTRAS(SC) if there is no evidence of disease progression

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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

- 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	4 to 5 hours

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K - References

Bachelot T, Ciruelos E, Schneeweiss A, et al. Preliminary safety and efficacy of first-line pertuzumab combined with trastuzumab and taxane therapy for HER2-positive locally recurrent or metastatic breast cancer (PERUSE). Ann Oncol 2019;30(5):766-773.

Baselga J, Cortés J, Kim SB, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. N Engl J Med 2012;366(2):109-19.

Kuemmel S, Tondini CA, Abraham J, et al. Subcutaneous trastuzumab with pertuzumab and docetaxel in HER2-positive metastatic breast cancer: Final analysis of MetaPHER, a phase IIIb single-arm safety study. Breast Cancer Res Treat. 2021 Jun;187(2):467-76.

Miles D, Ciruelos E, Schneeweiss A, et al. Final results from the PERUSE study of first-line pertuzumab plus trastuzumab plus a taxane for HER2-positive locally recurrent or metastatic breast cancer, with a multivariable approach to guide prognostication. Ann Oncol. 2021 Oct;32(10):1245-55.

Tan AR, Im SA, Mattar A, et al. Fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection plus chemotherapy in HER2-positive early breast cancer (FeDeriCa): a randomised, open-label, multicentre, non-inferiority, phase 3 study. Lancet Oncol. 2021 Jan;22(1):85-97.

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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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