Regimen Monograph

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

A - Regimen Name

FEC-D+PERT+TRAS Regimen

Fluorouracil-EPIrubicin-Cyclophosphamide then DOCEtaxel-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 Public Funding	trastuzumab New Drug Funding Program (Trastuzumab (Biosimilar) - Adjuvant Treatment for Breast Cancer) (NDFP Website)

back to top

B - Drug Regimen

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

FEC100 (Cycles 1 to 3):

fluorouracil	500 mg /m²	IV	Day 1
EPIrubicin	100 mg /m²	IV	Day 1
cyclophosphamide	500 mg /m²	IV	Day 1

THEN
DOCETAXEL (Cycles 4 to 6):

DOCEtaxel	100 mg /m²	IV	Day 1

Trastuzumab and pertuzumab are given for one year starting concurrently with DOCEtaxel:

Loading Dose (Cycle 4):

PERTuzumab	840 mg	IV	Day 1

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

trastuzumab	8 mg /kg	IV	Day 1

Maintenance Dose (Cycles 5+):

PERTuzumab	420 mg	IV	Day 1

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

trastuzumab	6 mg /kg	IV	Day 1

back to top

C - Cycle Frequency

REPEAT EVERY 21 DAYS

FEC100 X 3 cycles then DOCEtaxel+Pertuzumab+Trastuzumab for 3 cycles.

Refer to PERT+TRAS for cycles 7+.

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen:	High (FEC) Low (docetaxel)
Febrile Neutropenia Risk:	High Consider G-CSF prophylaxis for patients at high risk of febrile neutropenia. See G-CSF recommendations.

Other Supportive Care:

- Dexamethasone 8 mg bid po for 3 days starting 1 day prior to docetaxel (prevent anaphylaxis / fluid retention.)
- Consider filgrastim as primary prophylaxis for febrile neutropenia, especially during cycles 4 to 6 of FEC-D.
- Trastuzumab: Refer to Trastuzumab drug monograph for full details.

back to top

J - Administrative Information

Approximate Patient Visit	FEC: 1.5 hours; Docetaxel-Pertuzumab-Trastuzumab: 4.5 hours (1st cycle), 3 hours(subsequent cycles)
Pharmacy Workload (average time per visit)	33.22 minutes
Nursing Workload (average time per visit)	68.75 minutes

back to top

K - References

Coudert B, Asselain B, Campone M, et al. Extended benefit from sequential administration of docetaxel after standard fluorouracil, epirubicin, and cyclophosphamide regimen for node-positive breast cancer: the 8-year follow-up results of the UNICANCER-PACS01 trial. Oncologist 2012;17(7):900-9.

Cyclophosphamide, epirubicin, fluorouracil and docetaxel drug monographs, Cancer Care Ontario.

Mardarnas Y, Dent SF, Husain SF, et al. Real-world experience with adjuvant FEC-D chemotherapy in four Ontario regional cancer centres. Current Oncology 2011;18(3):119-25.

Roché H, Fumoleau P, Spielmann M, et al. Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: the FNCLCC PACS 01 Trial. JCO 2006; 24(36):5664-71.

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.

PEBC Advice Documents or Guidelines

- Optimal Systemic Therapy for Early Female Breast Cancer

April 2023 Updated DPD deficiency information in the Other Notes section

back to top

L - Other Notes

Patients should be tested for DPD deficiency before starting treatment with fluorouracil. Refer to the DPD Deficiency Guidance for Clinicians for more information.

In patients with unrecognized DPD deficiency, acute, life-threatening toxicity may occur; if acute grade 2-4 toxicity develops, treatment should be stopped immediately and permanent discontinuation considered based on clinical assessment of the toxicities.

back to top

M - Disclaimer

Regimen Abstracts

A 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). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

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 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.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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 provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability.

CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.

back to top