Regimen Monograph

A - Regimen Name

DOCE Regimen

DOCEtaxel

DOCE+TRAS Regimen

DOCEtaxel-Trastuzumab

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.
Rationale and Uses	For treatment of metastatic breast cancer
Supplementary Public Funding	**trastuzumab** New Drug Funding Program (Trastuzumab (Biosimilar) in combination with Docetaxel - Metastatic Breast Cancer) **trastuzumab** New Drug Funding Program (Trastuzumab (Biosimilar) with First Line Docetaxel - Metastatic Breast Cancer)

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trastuzumab
New Drug Funding Program (Trastuzumab (Biosimilar) - Second Line - Metastatic Breast Cancer)

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B - Drug Regimen

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

DOCEtaxel (Round to nearest 1 mg)	100 mg /m²	IV	Day 1

For patients with HER2 positive tumours, trastuzumab may be given concurrently and then as a single agent.

trastuzumab
Refer to TRAS (Breast - Advanced) regimen for details.

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

• Until disease progression or unacceptable toxicity occurs

• For patients with HER2 positive tumours, trastuzumab may be given concurrently and then as a single agent. Refer to TRAS (Breast - Advanced) regimen for details.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

Other Supportive Care:
Dexamethasone 8 mg bid po for 3 days starting 1 day prior to docetaxel (prevent anaphylaxis / fluid retention.) Trastuzumab: Refer to Trastuzumab drug monograph for full details.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and could be considered.

See TRAS (Breast - Advanced) regimen for details on trastuzumab dose modifications.

Dosage with toxicity

Toxicity (worst in previous cycle)	Docetaxel (% of previous dose)*
Febrile neutropenia / Grade 4 ANC ≥ 7 d	75%
Grade 3 skin/ neuro/ major organ/ non-hematologic toxicity	75%
Any occurrence of cystoid macular edema	Hold and investigate; refer patient promptly an ophthalmic examination. Discontinue if confirmed.
Grade 4 skin/ neuro/ major organ/ non-hematologic toxicity OR Recurrence of Grade 3 toxicity after prior dose reduction	Discontinue
* Do not retreat until ANC ≥ 1.5 x 10^9/L, platelets ≥ 100 x 10^9/L, and toxicity ≤ grade 2.	

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Hypersensitivity
Hypersensitivity reactions may occur within a few minutes following the initiation of docetaxel infusion.

Toxicity	**Action**
Mild hypersensitivity reaction	↓ infusion rate (and/ or hold) and use beta-agonists, antihistamines, antipyretics, and/or corticosteroids as appropriate. Consider premedication for next infusion.
Moderate hypersensitivity reaction	Hold and use beta-agonists, antihistamines, antipyretics, and/or corticosteroids as appropriate; complete infusion at ↓ rate if possible. Use premedication for next infusion.
Severe hypersensitivity reaction or Pulmonary Toxicity	Hold and manage symptoms aggressively with beta-agonists, antihistamines, antipyretics, and/or corticosteroids. Discontinue permanently and do not rechallenge

Hepatic Impairment

Docetaxel: Patients with hepatic impairment have a higher risk of severe adverse effects, including fatal gastrointestinal hemorrhage, sepsis and myelosuppression.

Bilirubin		**AST and/or ALT**		**Alkaline Phosphatase**	**Docetaxel dose**
> ULN	AND	Any	AND	Any	Do not treat. Discontinue if treatment already started.
Any	AND	> 1.5 X ULN	AND	> 2.5 x ULN	

Renal Impairment

No adjustment required.

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Dosage in the Elderly

For docetaxel, no adjustment required, but caution should be exercised in elderly patients with poor performance status.

For trastuzumab, no adjustment required; the risk of cardiac dysfunction and myelosuppression may be increased in elderly patients. The reported trials did not determine differences in efficacy between patients > 65 years versus younger patients.

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F - Adverse Effects

Refer to DOCEtaxel (± Trastuzumab) drug monograph(s) for additional details of adverse effects.

See TRAS (Breast - Advanced) regimen for details on trastuzumab adverse effects.

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Myelosuppression ± infection or bleeding (may be severe) • Hypersensitivity reactions (may be severe) • Fluid retention (may be severe) • Neuropathy (may be severe) • Cutaneous effects (including nails, may be severe) • Alopecia • GI (nausea, vomiting, stomatitis, diarrhea) • Fatigue • Musculoskeletal pain • Lacrimation/tear duct obstruction	• Secondary malignancies • Cardiotoxicity, arrhythmia • Pneumonitis • GI obstruction, perforation, hemorrhage • Venous thromboembolism • Arterial thromboembolism • DIC • Seizures • ↑ LFTs • Cystoid macular edema

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G - Interactions

Refer to DOCEtaxel (± Trastuzumab) drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to DOCEtaxel (± Trastuzumab) drug monograph(s) for additional details

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

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I - Recommended Clinical Monitoring

Also refer to TRAS (Breast - Advanced) regimen for details.

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- CBC, including nadir counts; baseline and before each dose
- Liver function tests; baseline and routine
- Regular toxicity assessment of infection, bleeding, neurotoxicity, fluid retention, hypersensitivity, lethargy, cutaneous reactions, thromboembolism, cardiovascular, musculoskeletal pain, ophthalmic, GI or respiratory effects; at each visit

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Approximate Patient Visit

DOCE	2 hours
DOCE+TRAS	First cycle: 3 hours; Subsequent cycles: 2 hours

Pharmacy Workload **(average time per visit)**

DOCE	23.936 minutes
DOCE+TRAS	33.025 minutes

Nursing Workload **(average time per visit)**

DOCE	54.167 minutes
DOCE+TRAS	71.667 minutes

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K - References

Chan S, Friedrichs K, Noel D, et al. Prospective randomized trial of docetaxel versus doxorubicin in patients with metastatic breast cancer. J Clin Oncol 1999; 17: 2341-54.

Docetaxel and trastuzumab drug monographs, Cancer Care Ontario.

Jones SE, Erban J, Overmoyer B, et al. Randomized phase III study of docetaxel compared with paclitaxel in metastatic breast cancer. J Clin Oncol. 2005 Aug 20;23(24):5542-51.

Nabholtz JM, Senn HJ, Bezwoda WR, et al. Prospective randomized trial of docetaxel versus mitomycin plus vinblastine in patients with metastatic breast cancer progressing despite previous anthracycline-containing chemotherapy. J Clin Oncol 1999;17:1413-24.

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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

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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 New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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