Regimen Monograph

A - Regimen Name

DOCEGEMC Regimen

DOCEtaxel-Gemcitabine

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	Treatment of anthracycline-resistant metastatic breast cancer, as an alternative to capecitabine-docetaxel

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B - Drug Regimen

DOCEtaxel	75 mg /m²	IV	Day 1
gemcitabine	1000 mg /m²	IV	Days 1 and 8

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity.

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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.)

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Dosage with toxicity

Dose on Day 1 of Cycle:

Non-Hematologic Toxicity		Hematologic Toxicity	Gemcitabine (% Full Dose)	Docetaxel (% full dose)
		Grade 4 neutropenia ≥ 7 days, or Febrile neutropenia, or Thrombocytopenic bleeding	75%*	75%*

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Non-Hematologic Toxicity		Hematologic Toxicity	Gemcitabine (% Full Dose)	Docetaxel (% full dose)
Grade 2 neurotoxicity			100%*	75%*
Grade 3 neurotoxicity			100%*	50%*, Discontinue if recurs.
Grade 4 neurotoxicity			100%*	Discontinue
Any occurrence of cystoid macular edema			No change	Hold and investigate; refer patient promptly to an ophthalmic examination. Discontinue if confirmed.
Other grade 3 related organ/non-hematologic			75% *	75% *
Other grade 4 related organ/non-hematologic			Discontinue	Discontinue
Day 8 holds on > 1 cycle			Discontinue or ↓ to 75% *	100%*
• Pneumonitis • Hemolytic Uremic Syndrome (HUS) • Stevens-Johnson syndrome (SJS) • Toxic epidermal necrolysis (TEN) • Capillary Leak Syndrome (CLS)			Discontinue	Discontinue

*Do not restart until toxicities have recovered to ≤ grade 1 and ANC ≥ 1.5 x 10^9/L and platelets ≥ 100 x 10^9/L.

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Dose on Day 8 of Cycle:

Toxicity on Day 8 of cycle					
Non–hematologic (related organ)		**Hematologic**			**Day 8 Gemcitabine (% Full Dose)**
		ANC ($x\ 10^6$/L)		**Platelets ($x\ 10^6$/L)**	
≤ grade 2	and	> 1000	and	> 100,000	100%
≤ grade 2	and	500-1000	or	50,000-100,000	Omit, or ↓ to 75%
Grade 3	or	< 500	or	< 50,000	Omit, ↓ to 75% at restart (if applicable) for non-hematologic toxicity
Grade 4 related organ Pneumonitis HUS SJS TEN CLS		-		-	Discontinue

Hepatic Impairment

	AST and/or ALT		**Alk Phosp**		**Bilirubin**	**Gemcitabine**	**Docetaxel dose**
Mild-moderate	> 1.5 X ULN	AND	> 2.5 x ULN			Use with caution	Do not treat
Severe	> 3.5 x ULN	OR	> 6 x ULN	OR	> ULN	Consider ↓ or Discontinue	Do not treat. Discontinue if treatment already started.

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Renal Impairment

Drug	Renal Impairment
Gemcitabine	Use with caution; close monitoring for occurrence of hemolytic uremic syndrome is required. No specific recommendations found
Docetaxel	No dose adjustment required

Dosage in the Elderly

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

For gemcitabine, clearance is lower in the elderly but no dose adjustment necessary.

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F - Adverse Effects

Refer to DOCEtaxel, gemcitabine drug monograph(s) for additional details of 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) • Fatigue, flu-like symptoms • Fluid retention (may be severe) • Neuropathy (motor or sensory) • Cutaneous effects (including nails, may be severe) • Alopecia • Proteinuria • GI (stomatitis, nausea/vomiting, diarrhea) • Musculoskeletal pain • ↑ LFTs (may be severe) • Lacrimation/tear duct obstruction	• Secondary malignancies • Pneumonitis/ARDS • Capillary leak syndrome • Cardiotoxicity, arrhythmia • Venous thromboembolism • Arterial thromboembolism • DIC • Seizures • Hemolytic uremic syndrome • Vasculitis • GI obstruction, perforation • Cystoid macular edema

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G - Interactions

Refer to DOCEtaxel, gemcitabine drug monograph(s) for additional details

• Gemcitabine is a known radiosensitizer.

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H - Drug Administration and Special Precautions

Refer to DOCEtaxel, gemcitabine drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

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; baseline and before each visit
- Baseline and regular liver and renal function tests
- Clinical toxicity assessment (including flu-like symptoms, hypersensitivity, fluid retention, thromboembolism, ophthalmic, cardiovascular, pulmonary, musculoskeletal pain, infection, bleeding, neurotoxicity, cutaneous changes, fatigue, GI); at each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- INR for patient receiving warfarin; Baseline and regular
- Urinalysis; Baseline and regular

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J - Administrative Information

Approximate Patient Visit	Day 1: 2 to 3 hours; Day 8: 0.75 hour

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K - References

Chan S, Romieu G, Huober J. Phase III study of gemcitabine plus docetaxel compared with capecitabine plus docetaxel for anthracycline-pretreated patients with metastatic breast cancer. J Clin Oncol 2009; 27(11): 1753-60.

Docetaxel, gemcitabine drug monograph, Cancer Care Ontario.

Fountzilas G, Dafni U, Dimopoulos MA, et al. A randomized phase III study comparing three anthracycline-free taxane-based regimens, as first line chemotherapy, in metastatic breast cancer: a Hellenic Cooperative Oncology Group study. Breast Cancer Res Treat 2009;115(1):87-99.

Nielsen DL, Bjerre KD, Jakobsen EH, et al. Gemcitabine plus docetaxel versus docetaxel in patients with predominantly human epidermal growth factor receptor 2-negative locally advanced or metastatic breast cancer: a randomized, phase III study by the Danish Breast Cancer Cooperative Group. J Clin Oncol 2011;29(36):4748-54.

Seidman AD, Brufsky A, Ansari RH, et al. Phase III trial of gemcitabine plus docetaxel versus capecitabine plus docetaxel with planned crossover to the alternate single agent in metastatic breast cancer. Ann Oncol 2011;22(5):1094-101.

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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 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.

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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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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.

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