Regimen Monograph

A - Regimen Name

DOXO(W) Regimen

DOXOrubicin (low dose)

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 advanced breast cancer

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B - Drug Regimen

DOXOrubicin	10-20 mg /m²	IV	Days 1, 8 and 15

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C - Cycle Frequency

REPEAT EVERY 21 TO 28 DAYS

Until evidence of non-response, disease progression or limited by cardiotoxicity risk

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Other Supportive Care:

Also refer to CCO Antiemetic Summary

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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 are in use at some centres.

Dosage with toxicity

Hematologic Toxicities: See Appendix 6 for general recommendations.

Hepatic Impairment

Bilirubin	% Usual Dose
1-2 x ULN	**REDUCE** to **75%** dose
2-4 x ULN	**REDUCE** to **50%** dose
> 4 x ULN	**OMIT** dose (Suggested action)

Renal Impairment

No adjustment required

Dosage in the Elderly

Use with caution.

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F - Adverse Effects

Refer to DOXOrubicin 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/bleeding (may be severe) • Nausea and vomiting • Alopecia • Mucositis, diarrhea • Increased LFTs • Rash • Skin hyperpigmentation	• Venous thromboembolism • Cardiotoxicity • Arrhthymia • Secondary malignancies • Vesicant • Photosensitivity • Hypersensitivity • Radiation recall reaction

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G - Interactions

Refer to DOXOrubicin drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to DOXOrubicin 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 cycle
- Liver function tests; baseline and regular
- Cardiac function tests (Echo, RNA and/or MUGA scans) for all patients with cardiac risk factors (including prior trastuzumab or patients at or above threshold dose levels); baseline and periodic
- Clinical toxicity assessment for stomatitis, nausea, vomiting, injection-site reactions, skin and cardiac symptoms; 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	0.5 hour
Pharmacy Workload (average time per visit)	16.415 minutes
Nursing Workload (average time per visit)	41.667 minutes

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K - References

Carmo-Pereira J, Costa FO, Henriques E, et al. A comparison of two doses of adriamycin in the primary chemotherapy of disseminated breast carcinoma. Br J Cancer 1987 Oct:56(4): 471-473.

Doxorubin drug monograph, Cancer Care Ontario.

Gasparini G1, Dal Fior S, Panizzoni GA, et al. Weekly epirubicin versus doxorubicin as second line therapy in advanced breast cancer. A randomized clinical trial. Am J Clin Oncol 1991;14(1):38-44.

Richards MA, Hopwood P, Ramirez AJ, et al. Doxorubicin in advanced breast cancer: influence of schedule response, survival and quality of life. Eur J Cancer 1992;28A(6-7): 1023-1028.

October 2017 edited cycle frequency (aligned with ST-QBP)

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L - Other Notes

If Doxorubicin given in higher dose q21 days, see DOXO regimen.

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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.

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.

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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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