Regimen Monograph

A - Regimen Name

CISPDOCE Regimen

CISplatin-DOCEtaxel

Disease Site	Lung - Non-Small Cell
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 locally advanced or metastatic non-small cell lung cancer

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B - Drug Regimen

DOCEtaxel	75 mg /m²	IV	Day 1
CISplatin	75 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a usual total of 4 to 6 cycles in responding patients unless disease progression or unacceptable toxicity occurs

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D - Premedication and Supportive Measures

Antiemetic Regimen: High

Other Supportive Care:

- Dexamethasone 8 mg bid po for 3 days starting 1 day prior to docetaxel (prevent anaphylaxis / fluid retention.)
- Standard regimens for Cisplatin premedication and hydration should be followed. Refer to Cisplatin monograph

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 have been adapted from clinical trials or product monographs and could be considered. Refer to Appendix 6 for general recommendations.

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Dosage with toxicity

Toxicity / Counts x 10^9/L		Toxicity / Counts x 10^9/L	Cisplatin[1] (% previous dose)	Docetaxel[1] (% previous dose)
Febrile Neutropenia	Or	Grade 4 ANC ≥ 7 d	75%[1]	75%[1]
Grade 2 neurotoxicity			75%	100%; monitor
Grade 3 rash	Or	Grade 3 Neurotoxicity	100% for rash. Discontinue for neurotoxicity.	Restart at 75%.[1] Discontinue if recurs
Cystoid macular edema			No change	Hold and investigate; refer patient promptly an ophthalmic examination. Discontinue if confirmed.
Other Grade 3 organ / non-hematologic			75%[1]	75%[1]
Grade 4 organ / non-hematologic			Discontinue	Discontinue

[1]Prior to retreatment, toxicity should have recovered to ≤ grade 2 and ANC ≥ 1.5 x 10^9/L and platelets ≥ 100 x 10^9/L.

Hepatic Impairment

	AST and/or ALT		Alk Phosp		Bilirubin	Cisplatin	Docetaxel dose
Mild-moderate	> 1.5 X ULN	AND	> 2.5 x ULN			No change	Do not treat
Severe	> 3.5 x ULN	OR	> 6 x ULN	OR	> ULN		Do not treat. Discontinue if treatment already started.

Renal Impairment

Creatinine Clearance	Cisplatin (% previous dose)	Docetaxel
46-60 mL/min	75%	No change
30-45 mL/min	50%	
< 30 mL/min	OMIT	

Dosage in the Elderly

For docetaxel, dosage adjustment is not required, but caution should be exercised in elderly patients with poor performance status who are receiving docetaxel.

Geriatric patients may be at higher risk of developing nephrotoxicity, ototoxicity/neurotoxicity or hematologic adverse effects with cisplatin.

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F - Adverse Effects

Refer to DOCEtaxel, CISplatin 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) • Hypersensitivity reactions (may be severe) • Musculoskeletal pain • Fluid retention (may be severe) • Neuropathy (including ototoxicity) • Cutaneous (skin and nails) • Fatigue • GI (nausea, stomatitis, diarrhea)	• Secondary malignancies • Pneumonitis • Arterial Thromboembolism • Venous Thromboembolism • Thrombotic microangiopathy • Hemolytic-uremic Syndrome • GI perforation / obstruction • Arrhythmia, heart failure • DIC • Raynaud's syndrome

• Alopecia • Nephrotoxicity • Fatigue • Electrolyte abnormalities • Lacrimation / lacrimal duct obstruction	• Cystoid macular edema

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G - Interactions

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

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H - Drug Administration and Special Precautions

Refer to DOCEtaxel, CISplatin 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

- Baseline and regular CBC.
- Baseline and regular renal function tests (including electrolytes and magnesium) and urinalysis
- Baseline and regular liver functions tests
- Clinical toxicity assessment (including infection, bleeding, neurologic, ototoxicity, hypersensitivity, fatigue, GI, cutaneous effects, fluid retention, respiratory, musculoskeletal pain, thromboembolism, ophthalmic)

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

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J - Administrative Information

Approximate Patient Visit	4 to 5 hours
Pharmacy Workload (average time per visit)	49.523 minutes
Nursing Workload (average time per visit)	64.833 minutes

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K - References

Cisplatin and docetaxel drug monographs, Cancer Care Ontario.

Fossella F, Pereira J, von Pawel J, et al. Randomized, multinational, phase III study of docetaxel plus platinum combinations versus vinorelbine plus cisplatin for advanced non-small-cell lung cancer: The TAX 326 study group. JCO 21(16): 3016-3024, 2003.

Schiller JH, Harrington D, Belani CP, Langer C, Sandler A, Krook J, et al. Comparison of four chemotherapy regimens for advanced non-small-cell lung cancer. New Engl J Med 2002;346:92-8.

PEBC Advice Documents or Guidelines

- Systemic Treatment for Patients with Advanced Non-Small Cell Lung Cancer

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L - Other Notes

There is no convincing evidence that any new agent (gemcitabine, vinorelbine, docetaxel, paclitaxel, irinotecan, pemetrexed) in combination with platinum is superior to any other platinum plus new agent combination.

For patients receiving platinum-based doublet therapy, a recommendation in favour of cisplatin over carboplatin is made based on a probable modest improvement in survival and an improvement in response. Cisplatin regimens result in more frequent nausea/vomiting and nephropathy, while thrombocytopenia is worse with carboplatin. Given the poor prognosis in this population, the relative toxicities and QOL differences should be given strong consideration.

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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.

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