Regimen Monograph

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A - Regimen Name

CISP(RT-D) Regimen

CISplatin (low dose)

Disease Site Head and Neck

Intent 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.

Rationale and Uses

Treatment of locally advanced head and neck cancer

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B - Drug Regimen			
<u>CISplatin</u>	6 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT DAILY concurrent with radiotherapy

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Febrile Neutropenia

Low

Risk:

Other Supportive Care:

Also refer to <a>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

No adjustment required.

Renal Impairment

Creatinine clearance or Serum creatinine	Action
If CrCl = 0.5-1.0mL/sec or Serum Creatinine=136-185µmol/L	REDUCE Cisplatin* to 50% dose
If CrCl < 0.5mL/min or	OMIT Cisplatin dose
Serum Creatinine>185µmol/L	

^{*}Upon the discretion of the prescriber, less dose reduction may be suggested. See CISPLATIN drug monograph.

Dosage in the Elderly

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 CISplatin drug monograph(s) for additional details of adverse effects

Concurrent Cisplatin and radiotherapy can lead to moderate to severe stomatitis affecting oral intake while on treatment, hence consideration should be made for feeding tube insertion to maintain nutrition.

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life Threatening
 Nausea and vomiting Nephrotoxicity (may be severe), elecotrolyte abnormalities Neurotoxicity and ototoxicity (may be severe), dysguesia Myelosuppression ± infection / bleeding Reproductive risk Stomatitis 	 Arterial thromboembolism Arrythmia Hemolytic uremic syndrome, vasculitis SIADH Myelopathy, optic neuritis Leukemia Seizures Hypersensitivity

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G - Interactions

Refer to CISplatin drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to 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

- CBC; baseline and before each cycle
- Baseline and regular liver and renal function (including electrolytes and magnesium) tests
- Clinical toxicity assessment (including stomatitis, neurotoxicity and ototoxicity); at each visit
- Grade toxicity using the current <u>NCI-CTCAE</u> (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Give low-dose cisplatin daily prior to radiation.

Approximate Patient Visit 1 hour

Pharmacy Workload (average time per visit) 9.749 minutes

Nursing Workload (average time per visit) 41.667 minutes

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K - References

Cisplatin drug monograph, Cancer Care Ontario.

Jeremic B, Shibamoto Y, Milicic B, et al. Hyperfractionated radiation therapy with or without concurrent low-dose daily cisplatin in locally advanced squamous cell carcinoma of the head and neck: A prospective randomized trial. J Clin Oncol 2000; 18: 1458-64

Jeremic B, Milicic B, Dagovic A, et al. Radiation therapy with or without concurrent low-dose daily chemotherapy in locally advanced, nonmetastatic squamous cell carcinoma of the head and neck. J Clin Oncol. 2004;22(17):3540-8

Wolff HA, Overbeck T, Roedel RM, et al. Toxicity of daily low dose cisplatin in radiochemotherapy for locally advanced head and neck cancer. J Cancer Res Clin Oncol 2009;135(7):961-7.

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

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