Regimen Monograph

A - Regimen Name

CISP(RT-W) Regimen

CISplatin (weekly)

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

CISplatin	40 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT WEEKLY concurrent with radiotherapy

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Febrile Neutropenia Risk: Low

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

No adjustment required.

Renal Impairment

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

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

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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 NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Approximate Patient Visit	2 to 3 hours
Pharmacy Workload (average time per visit)	21.749 minutes
Nursing Workload (average time per visit)	41.667 minutes

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K - References

Cisplatin drug monograph, Cancer Care Ontario.

Bachaud JM, Cohen-Jonathan E, Alzieu C, David JM, Serrano E, Daly-Schveitzer N. Combined postoperative radiotherapy and weekly cisplatin infusion for locally advanced head and neckcarcinoma: final report of a randomized trial. Int J Radiat Oncol Biol Phys. 1996 Dec 1;36(5):999-1004.

Chan AT, Leung SF, Ngan RK, Teo PM, et al. Overall survival after concurrent cisplatin-radiotherapy compared with radiotherapy alone in locoregionally advanced nasopharyngeal carcinoma. J Natl Cancer Inst. 2005 Apr 6;97(7):536-9.

Fountzilas G, Ciuleanu E, Bobos M, et al. Induction chemotherapy followed by concomitant radiotherapy and weekly cisplatin versus the same concomitant chemoradiotherapy in patients with nasopharyngeal carcinoma: a randomized phase II study conducted by the Hellenic Cooperative Oncology Group (HeCOG) with biomarker evaluation. Ann Oncol. 2012 Feb;23(2):427-35.

Tsan DL, Lin CY, Kang CJ, et al. The comparison between weekly and three-weekly cisplatin delivered concurrently with radiotherapy for patients with postoperative high-risk squamous cell carcinoma of the oral cavity. Radiat Oncol 2012;7:215.

PEBC Advice Documents or Guidelines

- The Management of Head and Neck Cancer in Ontario
- Systemic Therapy in the Curative Treatment of Head and Neck Squamous Cell Cancer

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L - Other Notes

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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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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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