CISP(RT-W) Regimen
CISplatin (weekly)

Disease Site: Genitourinary - Bladder

Intent: Adjuvant
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: As a radiosensitizer concurrent with pelvic radiotherapy in patients with localized muscle invasive transitional cell bladder cancer, who decline cystectomy or who are not medically operable.

B - Drug Regimen

**CISplatin** 40 mg /m² IV over 1 hour Day 1
C - Cycle Frequency

REPEAT WEEKLY
Concurrent with radiotherapy

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Febrile Neutropenia
Risk: Low

Other Supportive Care:
Standard regimens for Cisplatin premedication and hydration should be followed. Refer to Cisplatin monograph.

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.

Dosage with toxicity

<table>
<thead>
<tr>
<th>Worst Toxicity in Previous Cycle</th>
<th>Dose for next cycle*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 4 platelets, grade 4 ANC ≥ 5 days, thrombocytopenic bleeding or febrile neutropenia</td>
<td>↓ 25%</td>
</tr>
<tr>
<td>Grade 2 neurotoxicity /ototoxicity</td>
<td>↓ 25%</td>
</tr>
<tr>
<td>Grade 3 or 4 neurotoxicity/ototoxicity</td>
<td>Discontinue</td>
</tr>
<tr>
<td>Other grade 3 non-hematologic/organ toxicity</td>
<td>↓ 25%</td>
</tr>
<tr>
<td>Other grade 4 non-hematologic/organ toxicity</td>
<td>Discontinue</td>
</tr>
<tr>
<td>Worst Toxicity in Previous Cycle</td>
<td>Dose for next cycle*</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Hemolysis, optic neuritis, arterial thromboembolism, severe hypersensitivity reactions, grade 3 or 4 ↑ LFTs</td>
<td>Discontinue</td>
</tr>
</tbody>
</table>

* Do not retreat until platelets ≥100 x 10^9/L, ANC ≥ 1.5 x 10^9/L, toxicity has recovered to ≤ grade 2 (grade 1 for neurotoxicity) and creatinine ≤ ULN.

**Hepatic Impairment**

No adjustment required.

**Renal Impairment**

In general, renal function should have normalized before patients are retreated. If continued treatment is considered to be mandatory, the following dose modifications could be considered at the physician's discretion. (Continued on next page)

<table>
<thead>
<tr>
<th>Creatinine clearance</th>
<th>% previous dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>46-60</td>
<td>75%</td>
</tr>
<tr>
<td>30-45</td>
<td>Hold or 50%</td>
</tr>
<tr>
<td>&lt;30</td>
<td>Discontinue</td>
</tr>
</tbody>
</table>

**Dosage in the Elderly**

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

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

<table>
<thead>
<tr>
<th>Most Common Side Effects</th>
<th>Less Common Side Effects, but may be Severe or Life Threatening</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Myelosuppression ± infection / bleeding</td>
<td>• Arterial thromboembolism</td>
</tr>
<tr>
<td>• Nausea and vomiting</td>
<td>• Arrhythmia</td>
</tr>
<tr>
<td>• Nephrotoxicity (may be severe)</td>
<td>• Hemolytic uremic syndrome</td>
</tr>
<tr>
<td>• Electrolyte abnormalities</td>
<td>• Secondary malignancies</td>
</tr>
<tr>
<td>• Neurotoxicity and ototoxicity (may be severe)</td>
<td>• Seizures</td>
</tr>
<tr>
<td>• Hyperuricemia</td>
<td>• Hypersensitivity</td>
</tr>
<tr>
<td>• Reproductive risk</td>
<td>• Hemolysis</td>
</tr>
<tr>
<td></td>
<td>• Optic neuritis</td>
</tr>
<tr>
<td></td>
<td>• Vasculitis</td>
</tr>
</tbody>
</table>

G - Interactions

Refer to CISplatin drug monograph(s) for additional details

H - Drug Administration and Special Precautions

Refer to CISplatin drug monograph(s) for additional details

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 dose
- Renal function tests; baseline and before each dose
- Electrolytes, including magnesium, sodium, potassium, phosphate and calcium;
baseline and regular

- Audiogram; baseline and as clinically indicated
- Clinical toxicity assessment of infection, bleeding, nausea/vomiting, neurotoxicity, ototoxicity, thromboembolism; at each visit

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

Suggested Clinical Monitoring

- Audiogram; periodic
- Liver function tests; baseline and regular

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

K - References


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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