**NCCP Chemotherapy Regimen**

**CISplatin (100mg/m²) with Radiotherapy (RT)-21 day**

**INDICATIONS FOR USE:**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>*Reimbursement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemoradiation treatment for locally advanced (stage III to IV) squamous cell carcinoma (SCC) of the head and neck</td>
<td>C76</td>
<td>00387a</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

*If the reimbursement status is not defined*, the indication has yet to be assessed through the formal HSE reimbursement process.

**TREATMENT:**

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patient’s individual clinical circumstances.

CISplatin is administered once every 21 days with concurrent radiotherapy for 3 cycles.

Facilities to treat anaphylaxis MUST be present when the chemotherapy is administered.

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CISplatin</td>
<td>100mg/m²</td>
<td>IV Infusion</td>
<td>500-1000ml NaCl 0.9% over 2 hours (Pre and Post hydration therapy required)**</td>
<td>Every 21 days</td>
</tr>
</tbody>
</table>

*Pre and post hydration therapy required for CISplatin*

See local hospital policy recommendations.

Suggested prehydration for CISplatin therapy:

1. Administer 10mmol magnesium sulphate (MgSO₄) (±-KCl 20mmol/L if indicated) in 1000 mL sodium chloride 0.9% over 60 minutes.
2. Administer CISplatin as described above.

Post hydration: Administer 1000 ml 0.9% NaCl over 60mins

Mannitol 10% may be used to as per local policy to induce diuresis, although there is no conclusive evidence that this is required. The routine use of furosemide to increase urine flow is not recommended unless there is evidence of fluid overload.

CISplatin (radiosensitizer) – Radiotherapy

Since CISplatin is used in this protocol as a radiosensitising agent, it is to be administered on a day on which radiotherapy is delivered. Radiotherapy should start after CISplatin infusion is completed. If radiotherapy is cancelled on the CISplatin day, do not give CISplatin that day and postpone chemotherapy until radiation therapy resumes.

**ELIGIBILITY:**

- Indications as above
- ECOG 0-2
- Adequate hepatic, renal, and bone marrow function

**EXCLUSIONS:**

- Hypersensitivity to CISplatin or any of the excipients
- Moderate/severe renal impairment (creatinine clearance < 60 mL/min)
- Significant hearing impairment/tinnitus
- Pregnancy
- Lactation
PRESCRIPTIVE AUTHORITY:
The treatment plan must be initiated by a Consultant Medical Oncologist

TESTS:
Baseline tests:
FBC, liver and renal profiles
Audiology and creatinine clearance if clinically indicated.

Regular tests:
FBC, liver and renal profiles prior to each cycle.

Disease monitoring:
Disease monitoring should be in line with the patient’s treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:
- Any dose modification should be discussed with a Consultant.

Haematological:
Table 1: Dose modification of CISplatin in haematological toxicity

<table>
<thead>
<tr>
<th>ANC (x10^9 /L)</th>
<th>Platelets (x10^9 /L)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥1.5</td>
<td>and</td>
<td>100%</td>
</tr>
<tr>
<td>1 -1.49</td>
<td>or</td>
<td>75%</td>
</tr>
<tr>
<td>&lt;1</td>
<td>or</td>
<td>Delay chemoradiation until recovery</td>
</tr>
</tbody>
</table>

Renal and Hepatic Impairment:
Table 2: Dose modification of CISplatin in renal and hepatic impairment

<table>
<thead>
<tr>
<th>Renal Impairment</th>
<th>Dose</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CrCl (ml/min)</td>
<td></td>
<td>No dose modifications for hepatic impairment</td>
</tr>
<tr>
<td>≥60</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>45-59</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>&lt;45</td>
<td>Hold CISplatin or delay with additional IV fluids</td>
<td></td>
</tr>
</tbody>
</table>

Management of adverse events:
Table 3: Dose Modification of CISplatin for Adverse Events

<table>
<thead>
<tr>
<th>Adverse reactions</th>
<th>Recommended dose modification</th>
</tr>
</thead>
</table>
| Peripheral neuropathy  
Grade 2              | Reduce CISplatin dose by 25% |
| Grade 3 or 4       | Omit CISplatin               |

The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician. and is subject to HSE’s terms of use available at [http://www.hse.ie/eng/Disclaimer](http://www.hse.ie/eng/Disclaimer).

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SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: High (Refer to local policy).

PREMEDICATIONS:
Hydration prior and post CISplatin administration (Reference local policy or see recommendations above).

OTHER SUPPORTIVE CARE:
Prior to initiation of treatment, patients should be referred for consultation to Dentistry and Nutrition Services.

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS
The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- Hydration prior and post CISplatin administration (Reference local policy or see recommendations above).
- Neutropenia: Fever or other evidence of infection must be assessed promptly and treated appropriately.
- Renal toxicity: Renal toxicity is common with CISplatin. Encourage oral hydration.
- Ototoxicity and sensory neural damage should be assessed by history prior to each cycle.

DRUG INTERACTIONS:

- Avoid concurrent use of CISplatin with nephrotoxic drugs (e.g. aminoglycosides, furosemide, NSAIDS) due to additive nephrotoxicity. If necessary monitor renal function closely.
- Current drug interaction databases should be consulted for more information.

ATC CODE:
CISplatin L01XA01

REFERENCES:

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment</th>
<th>Approved By</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20/12/2016</td>
<td></td>
<td>Prof Maccon Keane</td>
</tr>
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</table>

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Tumour Group: Head and Neck
NCCP Regimen Code: 00387

NCCP Regimen: CISplatin 100mg/m² with Radiotherapy
Published: 20/12/2016
Review: 26/11/2020
Version number: 2

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Version number: 2

Updated to new NCCP template. Updated with revised hydration regimen for CISplatin

Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

1 ODMS – Oncology Drug Management System
CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes
Further details on the Cancer Drug Management Programme is available at;
http://www.hse.ie/eng/services/list/5/cancer/profinfomedonc/cdmp/.

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