**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>Locally-regionally recurrent/metastatic nasopharyngeal cancer not</td>
<td>C11</td>
<td>00514a</td>
<td>Hospital</td>
</tr>
<tr>
<td>amenable for local curative therapy.</td>
<td></td>
<td></td>
<td></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.

Facilities to treat anaphylaxis MUST be present when Gemcitabine is administered.

Gemcitabine is administered once weekly for 2 consecutive weeks followed by a 1 week pause (1 cycle = 21 days) for a maximum of 6 cycles or until disease progression or unacceptable toxicity develops.

<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 and 8</td>
<td>Gemcitabine</td>
<td>1250mg/m²</td>
<td>IV infusion</td>
<td>250ml NaCl 0.9% over 30mins</td>
<td>Every 21 days</td>
</tr>
</tbody>
</table>

**ELIGIBILITY:**

- Indications as above
- ECOG 0-2

**EXCLUSIONS:**

- Hypersensitivity to gemcitabine or any of the excipients
- Breast feeding

**PRESCRIPTIVE AUTHORITY:**

The treatment plan must be initiated by a Consultant Medical Oncologist

**TESTS:**

- **Baseline tests:**
  - FBC, renal and liver profile

- **Regular tests:**
  - FBC prior to each treatment
  - Renal and liver profile prior to each cycle

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**NCCP Regimen:** Gemcitabine (1250mg/m²) Monotherapy - 21 day

Published: 07/11/2018
Review: 07/11/2020
Version number: 1

Tumour Group: Head and Neck
NCCP Regimen Code: 00514
ISM0 Contributor: Prof Maccon Keane

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).

This information is valid only on the day of printing, for any updates please check [www.hse.ie/NCCPchemoregimens](http://www.hse.ie/NCCPchemoregimens).
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:**
Prior to commencing a new treatment cycle (i.e. day 1), ANC must be ≥1.0 x 10^9/L and platelets ≥100 x 10^9/L.

**Table 1: Dose modifications for gemcitabine within a cycle (i.e day 8)**

<table>
<thead>
<tr>
<th>ANC (x 10^9 /L)</th>
<th>Platelet count (x 10^9 /L)</th>
<th>Other toxicity</th>
<th>Recommended dose of Gemcitabine</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥1</td>
<td>and ≥100</td>
<td></td>
<td>100 %</td>
</tr>
<tr>
<td>0.5 - 1</td>
<td>or 50-100</td>
<td></td>
<td>75%</td>
</tr>
<tr>
<td>&lt; 0.5</td>
<td>or &lt;50</td>
<td></td>
<td>Omit. Do not restart treatment until ANC ≥ 0.5 and platelets ≥ 50</td>
</tr>
<tr>
<td>ANC &lt; 0.5 for ≥ 5 days or ANC &lt; 0.1 for ≥3 days or Any incidence of febrile neutropenia</td>
<td>or &lt; 25</td>
<td>or cycle delay of &gt;1 week due to any toxicity</td>
<td>Reduce dose to 75% of the original cycle initiation dose for all subsequent cycles.</td>
</tr>
</tbody>
</table>

**Renal and Hepatic Impairment:**

**Table 2: Dose modification of Gemcitabine in renal and hepatic impairment**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>Cr Cl (ml/min)</td>
<td>AST elevations do not seem to cause dose limiting toxicities. If bilirubin &gt; 27 micromol/L, initiate treatment with dose of 800 mg/m^2.</td>
</tr>
<tr>
<td>≥30</td>
<td>100%</td>
<td>Consider dose reduction clinical decision</td>
</tr>
<tr>
<td>&lt;30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Management of adverse events:**

**Table 3: Dose Modification of gemcitabine for Adverse Events**

<table>
<thead>
<tr>
<th>Adverse reactions</th>
<th>Recommended dose modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade ≥ 2 Pneumonitis</td>
<td>Discontinue gemcitabine</td>
</tr>
<tr>
<td>Grade &gt; 3 Non-haematological toxicity (except nausea/vomiting)</td>
<td>Therapy with gemcitabine should be withheld (until toxicity has resolved to grade ≤ 1) and may be resumed with 50% dose reduction or treatment discontinued at discretion of prescribing consultant.</td>
</tr>
<tr>
<td>Grade &gt; 4 Non-haematological toxicity</td>
<td>Discontinue treatment</td>
</tr>
</tbody>
</table>

**NCCP Regimen:** Gemcitabine (1250mg/m^2)
Monotherapy - 21 day

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SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:
Gemcitabine - Low (Refer to local policy).

PREMEDICATIONS: None usually required

OTHER SUPPORTIVE CARE: No specific recommendations

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

- **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated appropriately.
- **Pulmonary Toxicity**: Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.
- **Cardiovascular**: Due to the risk of cardiac and/or vascular disorders with Gemcitabine, particular caution must be exercised with patients presenting a history of cardiovascular events.
- **Irreversible renal failure**: In association with haemolytic uraemic syndrome may occur rarely with gemcitabine. Use caution with pre-existing renal impairment.

DRUG INTERACTIONS:
- Current drug interaction databases should be consulted for more information.

ATC CODE:
Gemcitabine L01BC05

REFERENCES:

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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i This indication is outside the licensed indications for Gemcitabine in Ireland. Patients should be informed of the unlicensed nature of this indication and consented to treatment in line with the hospital’s policy on the use of unlicensed medication and unlicensed or “off label” indications. Prescribers should be aware of their responsibility in communicating any relevant information to the patient and also in ensuring that the unlicensed or “off label” indication has been acknowledged by the hospital’s Drugs and Therapeutics Committee, or equivalent, in line with hospital policy.

ii 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/profinfo/medonc/cdmp/