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| <b>Indication</b>                     | <p><b>Untreated metastatic</b> (NOT locally advanced) pancreatic adenocarcinoma cancer only if other combination chemotherapies are unsuitable for the patient and they would otherwise have gemcitabine monotherapy (i.e. patient is not considered to be suitable for oxaliplatin and irinotecan-based combination chemotherapy).</p> <p>The following criteria apply:</p> <ul style="list-style-type: none"> <li>No previous systemic chemotherapy for pancreatic cancer unless given as a radiosensitiser in the neo-adjuvant or adjuvant setting and completed at least 6 months previously.</li> <li>Patient has a performance status of 0 or 1</li> <li>No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).</li> </ul> <p>For the first line treatment of <b>locally advanced non-metastatic</b> pancreatic adenocarcinoma cancer unsuitable for surgical resection.</p> <p>The following criteria apply:</p> <ul style="list-style-type: none"> <li>No previous systemic therapy for pancreatic cancer unless given in the neo-adjuvant or adjuvant setting and completed at least 6 months previously.</li> <li>Patient has a performance status of <math>\leq 1</math></li> </ul> <p>NB This indication is unlicensed. Trust policy regarding the use of unlicensed (off-label) treatments must be followed as the drugs in this treatment are not licensed in this indication.</p>                                                                                                                                                                                                                                                   |
| <b>Treatment Intent</b>               | Palliative treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Frequency and number of cycles</b> | <p>Repeat every 28 days</p> <p><b>Metastatic disease:</b> Continue until progressive disease or unacceptable toxicity or patient choice.</p> <p><b>Non-metastatic disease:</b> Continue until disease progression, unacceptable toxicity, patient choice or complete surgical resection.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Monitoring parameters</b>          | <ul style="list-style-type: none"> <li><b>Virology screening:</b> All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion.</li> <li>Monitor <b>U&amp;Es</b> and <b>LFTs</b> at each cycle.</li> <li>Monitor <b>FBC</b> at baseline, then day 1, 8 and 15 of each cycle.</li> <li><b>Day 1</b>, if neutrophils <math>&lt; 1.5</math> and / or PLT <math>&lt; 100</math> delay all treatment until recovery.</li> <li>Omit <b>day 8 or day 15</b> doses if neuts <math>&lt; 1.0</math> and/or platelets <math>&lt; 75</math>.</li> <li><b>Hepatic Impairment:</b> <ul style="list-style-type: none"> <li><b>Paclitaxel albumin bound:</b> For patients with mild <b>hepatic impairment</b> (total bilirubin <math>&gt; 1</math> to <math>\leq 1.5</math> x ULN and AST <math>\leq 10</math> x ULN), no dose adjustments are required. Insufficient data in moderate to severe hepatic impairment, d/w consultant.</li> <li><b>Gemcitabine:</b> If total bilirubin <math>&lt; 27 \mu\text{mol/L}</math>: no dose adjustment is needed.</li> <li>Total bilirubin <math>\geq 27 \mu\text{mol/L}</math>: either start at 80% of the original dose and increase the dose if tolerated or start with full dose with active monitoring.</li> </ul> </li> <li><b>Renal Impairment:</b> <ul style="list-style-type: none"> <li><b>Paclitaxel albumin bound:</b> No dose adjustments are required in mild to moderate renal</li> </ul> </li> </ul> |

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| Version            | 8          | Written by                                                                                                                                | M. Archer            |
| Supersedes version | 7          | Checked by                                                                                                                                | C. Waters<br>A. Ling |
| Date               | 19.08.2026 | Authorising consultant (usually NOG Chair)                                                                                                | S. Enefer            |

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|                     | <p>impairment (CrCl <math>\geq 30</math> to <math>&lt; 90</math> ml/min). Insufficient data in severe renal impairment (CrCl <math>&lt; 30</math> ml/min).</p> <ul style="list-style-type: none"> <li>○ <b>Gemcitabine:</b> If CrCl <math>\geq 30</math> ml/min no dose adjustment required. Use with caution in renal impairment – d/w consultant.</li> <li>• <b>Management of adverse reactions and Dose Modification:</b></li> <li>• When a <b>dose reduction</b> is required the first reduction should be to paclitaxel albumin bound 100mg/m<sup>2</sup> &amp; gemcitabine 800mg/m<sup>2</sup>, and the second reduction to paclitaxel albumin bound 75mg/m<sup>2</sup> &amp; gemcitabine 600mg/m<sup>2</sup>. If this is not tolerated treatment should be discontinued.</li> <li>• <b>Grade 3 or 4 febrile neutropenia</b>, withhold treatment until afebrile and neuts <math>\geq 1.5</math> and resume at next lower dose level of both drugs.</li> <li>• <b>Grade 3 or 4 peripheral neuropathy</b>, withhold paclitaxel albumin bound dose until <math>\leq</math> grade 1 and then resume at next lower dose level of paclitaxel albumin bound (no dose reduction of gemcitabine).</li> <li>• <b>Grade 2 or 3 cutaneous toxicity</b>, reduce to next lower dose level of both drugs. If cutaneous toxicity persists, discontinue treatment.</li> <li>• <b>Grade 3 mucositis or diarrhoea</b>, withhold doses until <math>\leq</math> grade 1, then resume at next lower dose level of both drugs.</li> <li>• Dose reduction should be considered if any other grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&amp;V and alopecia). Delay until resolution of toxicity to <math>\leq</math> grade 1.</li> <li>• <b>Cautions:</b> <ul style="list-style-type: none"> <li>○ Patients should be monitored for signs and symptoms of pneumonitis. After ruling out infectious etiology, permanently discontinue treatment with paclitaxel albumin bound and gemcitabine when a diagnosis of pneumonitis is made and initiate appropriate treatment.</li> <li>○ <b>Posterior Reversible Encephalopathy Syndrome (PRES)</b> has been rarely reported with gemcitabine. In patients developing PRES, treatment of specific symptoms including control of hypertension is recommended along with discontinuation of gemcitabine.</li> <li>○ <b>Haemolytic uraemic syndrome.</b> Gemcitabine should be discontinued at the first signs of any evidence of microangiopathic haemolytic anaemia, such as rapidly falling haemoglobin with concomitant thrombocytopenia, elevation of serum bilirubin, serum creatinine, blood urea nitrogen, or LDH.</li> <li>○ <b>Capillary leak syndrome.</b> Gemcitabine should be discontinued and supportive measures implemented if capillary leak syndrome develops during therapy. Capillary leak syndrome can occur in later cycles and has been associated in the literature with adult respiratory distress syndrome.</li> </ul> </li> <li>• <b>Driving and operating machinery:</b> Patients should be advised not to drive and use machines if they feel tired or dizzy.</li> <li>• <b>Pregnancy and contraception:</b> Please refer to the brand specific SPC for full guidance. Women of childbearing potential should use effective contraception and not consider pregnancy during treatment and after. Men should be advised to use effective contraception and not to conceive children during treatment and after.</li> <li>• <b>Drug interactions (for comprehensive list refer to BNF/SPC):</b></li> <li>• <b>Paclitaxel albumin bound:</b> use with caution in patients receiving concomitant inhibitors (e.g. ketoconazole, erythromycin, fluoxetine, cimetidine) or inducers (e.g. rifampicin, carbamazepine, phenytoin) of CYP2C8 or CYP3A4.</li> <li>• <b>Gemcitabine:</b> No specific interaction studies have been performed.</li> </ul> |
| <b>Reference(s)</b> | <p>KMCC protocol UGI-047 V7 <a href="https://www.england.nhs.uk/wp-content/uploads/2026/07/2423-commissioning-policy-gemcitabine.pdf">https://www.england.nhs.uk/wp-content/uploads/2026/07/2423-commissioning-policy-gemcitabine.pdf</a></p> <p>SPC accessed online Paclitaxel (Pazenir 5mg/ml) Teva UK Ltd 29.07.26</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

NB for funding information, refer to the CDF and NICE Drugs Funding List

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| Date               | 19.08.2026 | Authorising consultant (usually NOG Chair)                                                                                                | S. Enefer            |

**Repeat every 28 days**

| Day       | Drug                                                             | Dose                        | Route | Infusion Duration | Administration Details                                                                                                                                                                                          |
|-----------|------------------------------------------------------------------|-----------------------------|-------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b>  | Metoclopramide                                                   | 20mg                        | IV    | Bolus             |                                                                                                                                                                                                                 |
|           | Dexamethasone                                                    | 8mg                         | po    |                   |                                                                                                                                                                                                                 |
|           | <b>PACLITAXEL ALBUMIN BOUND (Abraxane ®/ Pazenir®/Apacross®)</b> | <b>125mg/m<sup>2</sup></b>  | IV    | 30 mins           | To be administered undiluted in a sterile PVC or non-PVC type intravenous bag. The use of specialized DEHP-free solution containers or administration sets is not necessary to prepare or administer infusions. |
|           | <b>GEMCITABINE</b>                                               | <b>1000mg/m<sup>2</sup></b> | IV    | 30 mins           | In sodium chloride 0.9% to a final concentration of 0.1mg/ml – 10mg/ml<br>If final volume >500ml consider extending infusion duration                                                                           |
| <b>8</b>  | Metoclopramide                                                   | 20mg                        | IV    | Bolus             |                                                                                                                                                                                                                 |
|           | Dexamethasone                                                    | 8mg                         | po    |                   |                                                                                                                                                                                                                 |
|           | <b>PACLITAXEL ALBUMIN BOUND (Abraxane ®/ Pazenir®/Apacross®)</b> | <b>125mg/m<sup>2</sup></b>  | IV    | 30 mins           | To be administered undiluted in a sterile PVC or non-PVC type intravenous bag. The use of specialized DEHP-free solution containers or administration sets is not necessary to prepare or administer infusions. |
|           | <b>GEMCITABINE</b>                                               | <b>1000mg/m<sup>2</sup></b> | IV    | 30 mins           | In sodium chloride 0.9% to a final concentration of 0.1mg/ml – 10mg/ml<br>If final volume >500ml consider extending infusion duration                                                                           |
| <b>15</b> | Metoclopramide                                                   | 20mg                        | IV    | Bolus             |                                                                                                                                                                                                                 |
|           | Dexamethasone                                                    | 8mg                         | po    |                   |                                                                                                                                                                                                                 |
|           | <b>PACLITAXEL ALBUMIN BOUND (Abraxane ®/ Pazenir®/Apacross®)</b> | <b>125mg/m<sup>2</sup></b>  | IV    | 30 mins           | To be administered undiluted in a sterile PVC or non-PVC type intravenous bag. The use of specialized DEHP-free solution containers or administration sets is not necessary to prepare or administer infusions. |
|           | <b>GEMCITABINE</b>                                               | <b>1000mg/m<sup>2</sup></b> | IV    | 30 mins           | In sodium chloride 0.9% to a final concentration of 0.1mg/ml – 10mg/ml<br>If final volume >500ml consider extending infusion duration                                                                           |

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| TTO   | Drug           | Dose | Route | Directions                                                                                                                                                                                                      |
|-------|----------------|------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Day 1 | Metoclopramide | 10mg | PO    | 10mg three times a day for 3 days after Day 1, Day 8 and Day 15, then 10mg up to 3 times a day as required (max. 30mg per day including 20mg pre-chemo dose).<br>Do not take for more than 5 days continuously. |
|       | Dexamethasone  | 4mg  | PO    | OM for 2 /7 after day 1, 8 & 15                                                                                                                                                                                 |

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