1. **Treatment & Condition**

   Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer

2. **Associated appraisal body & Summary of ruling**

   NICE Technology Appraisal guidance TA476 (September 2017)

   Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) with gemcitabine is recommended as an option for untreated metastatic adenocarcinoma of the pancreas in adults, only if:
   - other combination chemotherapies are unsuitable and they would otherwise have gemcitabine monotherapy and
   - the company provides nab-paclitaxel with the discount agreed in the patient access scheme.

3. **Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)**

   A Resource Impact Template was not provided as NICE advised that it is anticipated that the guidance will not have a significant implication on resources. This is because treatment is recommended for people for whom other combination chemotherapies are unsuitable and who would otherwise have gemcitabine monotherapy.

   It is the view of the local service that no more than five patients per annum would be suitable for treatment with paclitaxel under this TA.

4. **Patient Access Scheme Availability**

   (Yes/No)

   The company (Celgene) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nab-paclitaxel, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.

5. **Costs (before PAS if applicable)**

5.1 **Drug cost per patient per annum (for new and prevalent cases)**

   Nab-paclitaxel is given at a dose of 125mg/m$^2$ as an intravenous infusion on days 1, 8 and 15 of a 28-day cycle. The UK list price of nab-paclitaxel is £246 per 100mg vial.

   Treatment should be continued until disease progression or unacceptable toxicity (median time in pivotal trial 15 weeks).
Hence the average cost of treatment with nab-paclitaxel per patient, assuming
- a body surface area of 1.8m$^2$
- 15 weeks treatment ( = 3.75 cycles = 11 doses of nab-paclitaxel)

125mg x 1.8m$^2 = 225mg$ per dose = 3 x 100mg vials = 3 x £246 = £738 per dose.
11 x £738 = £8,118 per 15 weeks treatment per patient.

5.2 Infrastructure costs Per annum

Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process.

6. Expected implementation period

There is no impediment to immediate implementation for new patients.

7. Commissioning arrangements

This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis for a period of 12 months. After this time, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.

8. Monitoring arrangements

The HSCB cost per case process will generate quarterly reports on the number of applications.

HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units.

The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.

9. DoH (NI) Legislative/Policy Caveats

This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.