**HSCB Service Notification for the managed entry of new medicines and technologies**

Health and Social Care Board

| | |
|---|---|
| **1** | **Treatment & Condition**<br><br>Nivolumab for previously treated advanced renal cell carcinoma |
| **2** | **Associated appraisal body Summary of ruling**<br><br>NICE Technology Appraisal Guidance (TA417) November 2016<br><br>Nivolumab is recommended, within its marketing authorisation, as an option for previously treated advanced renal cell carcinoma in adults, when the company provides nivolumab with the discount agreed in the patient access scheme.<br><br>Nivolumab provides an option for previously treated advanced renal cell carcinoma in adults at second line or third line |
| **3** | **Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)*<br><br>According to the Resource Impact Template that accompanies TA417, it is estimated that approximately 11 people will be eligible for treatment with nivolumab to treat advance renal cell carcinoma annually in Northern Ireland.<br><br>This number is supported by local clinicians who estimated approximately 1 patient per month requiring treatment and also reflects the cost per case requests to date. It is therefore anticipated that 12 patients per annum in Northern Ireland will require treatment with nivolumab in line with this TA. |
| **4.** | **Patient Access Scheme Availability**<br><br>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nivolumab, 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)**<br><br>Nivolumab (Opdivo®) is a human monoclonal antibody that blocks an immune checkpoint protein receptor called programmed cell death protein 1 (PD‑1) to promote an anti-tumour response. Nivolumab 'as monotherapy is indicated for the treatment of advanced renal cell carcinoma after prior therapy in adults'. In this indication, nivolumab is given at dose of 3 mg/kg given intravenously every 2 weeks. The list price is £439 per 40-mg vial or £1,097 per 100-mg vial.<br><br>Assuming that:<br>• Average patient weight = 78kg (therefore nivolumab dose = 234mg = £2,633.00 per dose) |

| | |
|---|---|
| | • Patients receive one dose every 2 weeks<br>• Average treatment duration is 22 weeks<br><br>The average cost of a course of 22 weeks treatment = £28,963 per patient |
| 5.2 | **Total Drug Costs Per annum** |
| 5.3 | **Infrastructure costs Per annum**<br><br>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**<br><br>There is no impediment to immediate implementation for new patients. |
| **7.** | **Commissioning arrangements**<br><br>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 regime. |
| **8.** | **Monitoring arrangements**<br><br>The HSCB cost per case process will generate quarterly reports on the number of applications.<br><br>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.<br><br>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**<br><br>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. |