

1.	<p>Treatment & Condition</p> <p>Nivolumab with ipilimumab for untreated advanced renal cell carcinoma</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA581 (May 2019)</p> <p>Nivolumab with ipilimumab is recommended for use within the Cancer Drugs Fund as an option for adults with untreated advanced renal cell carcinoma that is intermediate- or poor-risk as defined in the International Metastatic Renal Cell Carcinoma Database Consortium criteria. It is recommended only if the conditions in the managed access agreement for nivolumab with ipilimumab are followed.</p>
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>By extrapolation from the Resource Impact Statement that accompanies NICE TA581, it is estimated that around 48 people per year in Northern Ireland with untreated advanced renal cell carcinoma that is intermediate- or poor-risk are eligible for treatment with nivolumab with ipilimumab.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Bristol-Myers Squibb) has commercial arrangements for nivolumab with ipilimumab. This makes nivolumab with ipilimumab available to the NHS with a discount. The size of the discount is commercial in confidence.</p> <p>HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the managed access agreement.</p>
5.	<p>Infrastructure Requirements</p> <p>Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process</p>
6.	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p>Commissioning arrangements</p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, 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</p>

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. The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.