

1.	<p>Treatment & Condition</p> <p>Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA462 (July 2017)</p> <p>Nivolumab is recommended, within its marketing authorisation, as an option for treating relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin, when the company provides nivolumab with the discount agreed in the patient access scheme.</p>
3.	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>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.</p> <p>It is the view of local clinicians that the number of patients eligible for treatment under TA462 would be in the region of 2 per annum. However there is the potential to fluctuate in any given year, but not significantly.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes/No</u>)</p> <p>The company (Bristol-Myers Squibb) 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.</p>
5.	<p>Costs (before PAS if applicable)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Nivolumab (Opdivo[®]) is given at a dose of 3mg/kg intravenously every 2 weeks. Treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient.</p> <p>The list price is £439.00 per 40mg vial or £1,097 per 100mg vial.</p> <p>Based on an average body weight of 70kg, the cost per 2-week cycle is £2,633 per patient (assuming no vial sharing). Thus if 27 cycles are given annually, the cost per patient per annum is £71,091.</p>

5.2	<p>Infrastructure costs Per annum</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 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.</p>
8.	<p>Monitoring arrangements</p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p> <p>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.</p> <p>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.</p>
9.	<p>DoH (NI) Legislative/Policy Caveats</p> <p>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.</p>