

1.	<p>Treatment & Condition</p> <p>Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease.</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA558 (January 2019)</p> <p>Nivolumab is recommended for use within the Cancer Drugs Fund as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the conditions in the managed access agreement are followed.</p>
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>By extrapolation from the figures in the Resource Impact statement that accompanies NICE TA558, it is estimated that 42 people per year in Northern Ireland with stage III melanoma with lymph node involvement or metastatic disease who have had complete resection are eligible for treatment with nivolumab.</p> <p>It is the view of local clinicians that due to current clinical practice the number of patients treated in NI would be in the region of 4 – 6 per annum. However, clinical practice may change in the future leading to an increase in patients being treated with this therapy.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Bristol–Myers Squibb) has a commercial arrangement. This makes pembrolizumab 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 arrangement.</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 on a cost-per-case (CPC) basis for as long as NICE indicates that funding via the Cancer Drugs Fund is appropriate.</p>
<p>8.</p>	<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 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> <p>Numbers of patients who received or are receiving treatment will be monitored by the HSC Board and reported to the Department of Health.</p>
<p>9.</p>	<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> <p>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.</p>