

1.	<p><b>Treatment &amp; Condition</b></p> <p>Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA428 (January 2017).</p> <p>Pembrolizumab (Keytruda<sup>®</sup>) is recommended as an option for treating locally advanced or metastatic PD-L1 -positive non-small-cell lung cancer (NSCLC) in adults who have had at least one chemotherapy (and targeted treatment if they have an epidermal growth factor receptor [EGFR]- or anaplastic lymphoma kinase [ALK]-positive tumour), only if:</p> <ul style="list-style-type: none"> <li>• pembrolizumab is stopped at 2 years of uninterrupted treatment and no documented disease progression, and</li> <li>• the company provides pembrolizumab with the discount agreed in the patient access scheme revised in the context of this appraisal</li> </ul>
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <p>The number of people in Northern Ireland estimated to have pembrolizumab each year for this indication (based on the NICE Resource Impact template that accompanies TA428) is 60 [56 patients in the second-line setting and 4 patients in the third-line setting].</p> <p>However it is the view of local clinicians that this is an overestimate and it is anticipated that approximately 10 patients per annum will be eligible for treatment in line with the TA. Treatment will be provided in the Cancer Centre and the North West Cancer Centres only.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p><b>(Yes/No)</b></p> <p>The manufacturer of pembrolizumab has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of pembrolizumab with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5.	<p><b>Costs (before PAS if applicable)</b></p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>Pembrolizumab is administered as an intravenous infusion at a dose of 2mg/kg every three weeks.</p> <p>Assuming an average body weight of 73.1kg (as per NICE) the dose administered is 146.2mg every three weeks</p>

	<p>Pembrolizumab is available at a list price of £1,315.00 per 50mg vial (excluding VAT). Hence, the cost per dose at the list price is 3 x £1,315.00 = £3,945.00</p> <p>In studies on the use of pembrolizumab, patients received an average of 8.5 cycles of treatment with pembrolizumab. Hence, the average cost of a course of treatment with pembrolizumab at the list price is 8.5 x £3,945.00 = £33,532.50 per patient.</p>
<b>5.2</b>	<p><b>Infrastructure costs Per annum</b></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>
<b>6.</b>	<p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>
<b>7.</b>	<p><b>Commissioning arrangements</b></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>
<b>8.</b>	<p><b>Monitoring arrangements</b></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>
<b>9.</b>	<p><b>DoH (NI) Legislative/Policy Caveats</b></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>