

<p>1</p>	<p>Treatment & Condition <i>(Title)</i></p> <p>Pembrolizumab (Keytruda®) for treating advanced melanoma after disease progression with ipilimumab.</p>
<p>2</p>	<p>Associated appraisal body <i>(NICE/SMC/Other)</i> & Summary of ruling <i>(to include indication, restrictions, other relevant information)</i></p> <p>NICE technology appraisal guidance TA357 (October 2015)</p> <p>Pembrolizumab is recommended as an option for treating advanced (unresectable or metastatic) melanoma in adults only:</p> <ul style="list-style-type: none"> • after the disease has progressed with ipilimumab and, for BRAF V600 mutation-positive disease, after both ipilimumab and a BRAF or MEK inhibitor and • when the company provides pembrolizumab with the discount agreed in the patient access scheme.
<p>3</p>	<p>Number of people in Northern Ireland expected to take up service/therapy <i>(including new cases per year)</i></p> <p>According to the Costing Template that accompanies TA357, it is expected that 17 people will be treated annually with pembrolizumab in line with this TA. However, it is the view of local clinicians that the expected volume of patients receiving pembrolizumab in line with this TA is in the region of 10. This is supported by actual usage data showing approximately 1 patient per month commencing Ipilimumab as 1st line treatment.</p> <p>Because Pembrolizumab is now also recommended for patients not previously treated with Ipilimumab, consequently it is likely that it will replace Ipilimumab for a proportion of patients (1st line). It is expected therefore that the number of people receiving Pembrolizumab after Ipilimumab (or Ipilimumab plus BRAF/MEK inhibitor) will decrease in year 2 and year 3. This will however be offset by the likely increase in the number receiving Pembrolizumab 1st line, consistent with TA366.</p> <p>There may be an initial upsurge from patients previously treated with Ipilimumab over the past few years and who have now progressed, but this should be mainly year 1 (10 per annum), and decline thereafter to probably 2 per annum at most, by year 3.</p>
<p>4</p>	<p>Patient Access Scheme availability</p> <p>The company 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	Costs <i>(before PAS if applicable)</i>												
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Pembrolizumab is administered intravenously for 30 minutes at a dose of 2 mg/kg every 3 weeks until disease progression or unacceptable toxicity. The acquisition cost of pembrolizumab is £1315 per 50mg vial.</p> <p>Based on a patient of average body weight (77.2kg), each dose (154mg) will require 4 vials of pembrolizumab at a cost of £5260.00 per dose.</p> <p>According to the NICE Costing Template, patients receive an average of 5.3 cycles per year. The annual cost per patient is therefore estimated as £27,878 (before any PAS discount)</p>												
5.2	<p>Infrastructure costs per patient 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>												
5.3	<p>Current in year costs</p> <p>In-year costs will be met by a cost per case arrangement.</p>												
5.4	<p>Recurrent overall costs per annum <i>(including additional costs)</i></p> <p>The estimated cost of implementation(before PAS discount) is estimated as follows:</p> <table border="1"> <thead> <tr> <th>Year</th> <th>Patients</th> <th>Costs</th> </tr> </thead> <tbody> <tr> <td>Year 1</td> <td>10</td> <td>£265,000</td> </tr> <tr> <td>Year 2</td> <td>5</td> <td>£127,000</td> </tr> <tr> <td>Year 3</td> <td>2</td> <td>£59,000</td> </tr> </tbody> </table>	Year	Patients	Costs	Year 1	10	£265,000	Year 2	5	£127,000	Year 3	2	£59,000
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Year 1	10	£265,000											
Year 2	5	£127,000											
Year 3	2	£59,000											
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>Implementation of NICE TA357 is unlikely to result in any cost savings.</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>Pembrolizumab will be formally commissioned by the HSCB/PHA by the Specialist Services Commissioning Team on a CPC basis for use in the Cancer Centre.</p>												

8	Monitoring arrangements <p>The HSCB IFR process will generate quarterly reports on the number of Cost Per Case applications which will be reviewed formally by the Specialist Services Commissioning Team on a quarterly basis.</p> <p>The HSCB currently reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and Cancer 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	DHSSPS Legislative/Policy Caveats <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>