

1	<p>Treatment & Condition</p> <p>Nivolumab for treating advanced (unresectable or metastatic) melanoma</p>																		
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance TA384 (February 2016)</p> <p>Nivolumab (Opdivo®) as monotherapy is recommended, within its marketing authorisation, as an option for treating advanced (unresectable or metastatic) melanoma in adults.</p>																		
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>The table below estimates the number of people eligible for treatment with nivolumab in Northern Ireland. It is based on the information provided by NICE in their Resource Impact Report which accompanies TA384.</p> <table border="1" data-bbox="245 994 1257 1406"> <thead> <tr> <th colspan="3">Number of people eligible for treatment in Northern Ireland with nivolumab</th> </tr> <tr> <th>Population</th> <th>Proportion</th> <th>Number of people</th> </tr> </thead> <tbody> <tr> <td>Total NI population</td> <td></td> <td>1,840,498</td> </tr> <tr> <td>Incidence of melanoma</td> <td>0.0211%</td> <td>388</td> </tr> <tr> <td>Advanced (unresectable, metastatic) melanomas</td> <td>10.00%</td> <td>39</td> </tr> <tr> <td>Total number of people eligible for treatment with nivolumab</td> <td></td> <td>39</td> </tr> </tbody> </table> <p>It is estimated that 39 people are eligible for treatment with nivolumab each year. However, as nivolumab is used to treat the same cohort of patients currently being treated with pembrolizumab 1st and 2nd line (TA366 and TA357), it is the view of local clinicians that as pembrolizumab is the preferred option for treatment it is anticipated that there will be little demand for the use of nivolumab. If nivolumab is to be used it will be in place of pembrolizumab (both 1st and 2nd line).</p> <p>It is estimated that no more than 4 patients will be treated with nivolumab.</p>	Number of people eligible for treatment in Northern Ireland with nivolumab			Population	Proportion	Number of people	Total NI population		1,840,498	Incidence of melanoma	0.0211%	388	Advanced (unresectable, metastatic) melanomas	10.00%	39	Total number of people eligible for treatment with nivolumab		39
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4	<p>Patient Access Scheme availability</p> <p>Not applicable</p>																		
5	<p>Costs (before PAS if applicable)</p>																		

<p>5.1</p>	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Nivolumab has a marketing authorisation as monotherapy 'for treating advanced (unresectable or metastatic) melanoma in adults'. It is administered intravenously over 60 minutes at a dose of 3 mg/kg every 2 weeks. The summary of product characteristics recommends that 'treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated'.</p> <p>The acquisition cost of nivolumab is £439 per 4 ml (40 mg) vial and £1097 per 10 ml (100 mg) vial (excluding VAT).</p> <p>The cost per person of nivolumab is as follows (based on an average body weight of 77.2kg):</p> <ul style="list-style-type: none"> • As first line treatment (patients receive an average of 15 cycles) total nivolumab cost = £39,510 • As second/third line treatment (patients receive an average of 11.5 cycles)total nivolumab cost = £30,291
<p>5.2</p>	<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>
<p>5.3</p>	<p>Current in year costs</p> <p>Depending on uptake but no more than £30k per annum.</p>
<p>5.4</p>	<p>Recurrent overall costs per annum (including additional costs)</p> <p>Only a small number of patients will be treated with this drug. Most patients will be treated with pembrolizumab 1st and 2nd line (TA366 and TA357).</p> <p>The drug has a higher cost than pembrolizumab, The additional cost is estimated at no more than £30k per annum.</p>
<p>5.5</p>	<p>Opportunities for cost savings and how these will be secured</p> <p>Cost savings are not anticipated.</p>
<p>6</p>	<p>Expected implementation period</p> <p>There is no impediment to implementation for new patients</p>
<p>7</p>	<p>Commissioning arrangements</p> <p>This drug 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	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	DHSSPS Legislative/Policy Caveats <i>(NICE guidance only)</i> 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.