

NICE TA 269 – Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation malignant melanoma

<p>1</p>	<p>Summary of NICE TA 269</p> <p>Vemurafenib is recommended as an option for treating BRAF V600 mutation-positive unresectable or metastatic melanoma only if the manufacturer provides vemurafenib with the discount agreed in the patient access scheme.</p>
<p>2</p>	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>The NICE costing template accompanying TA 269 indicates that 13 patients per year (based on standard assumptions) would be expected to take up treatment.</p> <p>A business case from the NICAN Drugs and Therapeutic Committee has indicated that approximately 22 patients per annum would be eligible for treatment with vemurafenib.</p> <p>Coincidentally, another regime for treatment of malignant melanoma has also been recommended by NICE in the same timescale. This is for TA 268 – Ipilimumab.</p> <p>As part of the engagement process with local clinician when exploring the delivery of new NICE recommended Technology Appraisals, the HSCB/PHA has considered submissions from the Northern Ireland Cancer Network, Drug and Therapeutic Committee.</p> <p>The volume of patients projected to benefit by NICaN from these regimes is considerably higher than that projected in the NICE costing templates for both of these regimes.</p> <p>The submissions made in respect of both TA 269 and TA 268 identified a cohort of 86 patients per annum with this condition. The NICaN submissions were forwarded as two individual, separate business cases for each of the two TAs but did not provide any information as to whether treatment for this cohort of patients would be potentially sequential between the two regimes or exclusive to one subset of eligible patients.</p> <p>Therefore, HSCB/PHA sought additional clarification from the NICaN D&T Committee specifically on:</p> <ul style="list-style-type: none"> • Rationale for significantly higher volume of patients with this specific condition that projected by NICE • Relationship between the two regimes identified through a care pathway or confirmation that the two regimes are exclusive to specific patient subsets.

	<p>Clinical advice indicates that there may be higher incidence of advanced / unresectable melanoma in the Northern Ireland population, some of which may be among patients diagnosed some years ago but among whom the disease has progressed. The number of patients eligible for these treatments as per the NICAN business cases appears to be higher than what would be indicated in the NICE costing templates The NICaN D&T Committee has advised that they are planning an audit on the first year of Cost Per Case use of these drugs and the results of this audit will be taken into account in service planning.</p> <p>Regarding the relationship between these 2 drugs, clinical advice is that when a a patient develops irresectable metastatic melanoma they will be considered for systemic therapy. If the tumour carries a mutation of the BRAF gene then it is suitable for Vemurafenib and this would be offered. If not then the patient is offered first-line chemotherapy (dacarbazine or temozolomide).</p> <p>When disease progression occurs then the patient will be considered for second line therapy which would be Ipilimumab if they are fit for that therapy. If not suitable for Ipilimumab then they would be considered for a second-line treatment with chemotherapy (particularly if they are taking steroids or have an auto-immune disease, which renders them unsuitable for Ipilimumab).</p> <p>Metastatic Disease</p> <p>First line BRAF +ve = vemurafenib BRAF -ve = DTIC/Temozolomide</p> <p>Second line Ipilimumab or second-line chemotherapy</p> <p>HSCB/PHA has reserved a level of funding adequate to address the demand for this regime in line with the NICaN D&T estimate to ensure that the higher estimate of projected demand can be resourced if required and the NICE TA introduced in line with Circular HSC (SQSD) 04/11. The regime is currently available on a cost per case basis and <u>no patient will be delayed</u> from commencing treatment pending finalisation of the business case.</p> <p>From August, 2012 to date, 6 requests for Vemurafenib have been approved by HSCB on a Cost Per Case basis.</p> <p>The final position will be closely monitored via a formal review of the cost per case applications by the specialist services commissioning team on a quarterly basis.</p>
<p>3</p>	<p>Costs</p> <p>Recurrent cost is estimated at £0.9m to £1.2m</p>
<p>3.1</p>	<p>Cost per patient per annum</p> <p>The NICaN D&T business case indicates that the total cost per patient per annum is</p>

	<p>£43,000. This is based on average treatment duration of 6 months. 22 patients would cost an additional £946k (before PAS).</p> <p>22 patients would cost an additional £1.2m as per the NICE costing template.</p>
3.2	<p>In year cost per patient per</p> <p>In year costs will be met through a cost per case arrangement and monitored pending finalisation of the recurrent business case.</p> <p>The expected in year costs are within the range above i.e. £0.9m to £1.2m depending on actual dosage and duration.</p>
3.3	<p>Cost savings and how these will be secured</p> <p>Not applicable</p>
3.4	<p>Recurrent overall cost</p> <p>The manufacturer of vemurafenib has agreed a patient access (PAS) with the Department of Health, in which a discount on the list price of vemurafenib is offered. The size of the discount is commercial in confidence. Belfast Trust will be expected to avail of this scheme.</p>
4	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients. Patients are already commencing treatment through a cost per case arrangement.</p>
5	<p>Commissioning arrangements</p> <p>This treatment will be delivered only in the Cancer Centre. Treatment for advanced melanoma is delivered in the Cancer Centre for all patients across the region.</p> <p>For monitoring purposes, commissioning arrangements for this regime will be via the Cost Per Case arrangement for a 12 month period and will be consolidated thereafter in line with the cost per case audit data.</p>
6	<p>Monitoring arrangements</p> <p>HSCB currently 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 regime 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>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>SSCT has a long established relationship with NICaN D&T and will continue regular interface with the committee to discuss the quarterly review of the cost per case applications and identify any necessary action.</p>
<p>7</p>	<p>DHSSPS 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.</p> <p>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>