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| 1   | <p><b>Treatment &amp; Condition</b> <i>(Title)</i></p> <p>Dabrafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma.</p>   |
| 2   | <p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal Guidance 321 (October 2014)</p> <p>Dabrafenib is recommended as an option for treating unresectable or metastatic BRAF V600 mutation-positive melanoma only if the company provides dabrafenib with the discount agreed in the patient access scheme.</p>   |
| 3   | <p><b>Number of people in Northern Ireland expected to take up service/therapy</b> <i>(including new cases per year)</i></p> <p>In the Costing Statement that accompanies TA321, NICE indicate that in England, the number of patients eligible for treatment with dabrafenib each year is approximately 1,100. On a pro rata basis this would approximate to 33 eligible patients annually in Northern Ireland.</p> <p>Dabrafenib provides another option for the group of patients who are BRAF V600 mutation-positive and it is similarly priced to the current treatment option, vemurafenib.</p> <p>Vemurafenib is recurrently funded to treat 22 patients at the NI Cancer Centre.</p> |
| 4   | <p><b>Patient Access Scheme availability</b></p> <p>The manufacturer of dabrafenib has agreed a patient access scheme with the Department of Health that makes dabrafenib available with a discount applied at the point of purchase or invoice. The size of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.</p>  |
| 5   | <p><b>Costs</b></p>  |
| 5.1 | <p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>The list price of dabrafenib is £1400 for a pack of 75-mg capsules (28 capsules per pack) and £933.33 for a pack of 50-mg capsules (28 capsules per pack) (excluding VAT; 'British national formulary' [BNF] edition 67). It is taken orally at a recommended dose of 150 mg twice daily.</p> <p>Hence the cost per patient per annum is £73k, before application of the PAS discount.</p>  |

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| <b>5.2</b> | <p><b>Infrastructure costs per patient per annum</b></p> <p>Current standard treatment for advanced (unresectable or metastatic) melanoma is dacarbazine, vemurafenib or ipilimumab. Dabrafenib is now another option in the treatment pathway. Both dacarbazine and ipilimumab are given by intravenous infusion; vemurafenib and dabrafenib are given orally.</p> <p>No additional infrastructure costs are expected with the introduction of this regimen.</p>   |
| <b>5.3</b> | <p><b>Current in year costs</b></p> <p>As Dabrafenib will be used to treat the same cohort of patients at the same stage of the pathway as Vemurafenib (which is recurrently commissioned and of equal cost to Dabrafenib), there will be no additional costs in implementing this regime. Clinicians will chose to treat patients with either Vemurafenib or Dabrafenib at their clinical discretion.</p>  |
| <b>5.4</b> | <p><b>Recurrent overall costs per annum</b> <i>(including additional costs)</i></p> <p>There will be no additional costs in introducing this regime as patients who are eligible for treatment with Dabrafenib are already eligible for treatment with Vemurafenib which has a similar cost.</p>  |
| <b>5.5</b> | <p><b>Opportunities for cost savings and how these will be secured</b></p> <p>Implementation of NICE TA321 is unlikely to result in any cost savings.</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 regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team on a CPC basis for use in the Cancer Centre. No additional funding will be allocated as this regimen provides another treatment option for this cohort of patients.</p>  |
| <b>8</b>   | <p><b>Monitoring arrangements</b></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>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 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> |

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**DHSSPS Legislative/Policy Caveats**

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.