

1	<p>Treatment & Condition</p> <p>Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma.</p>																		
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA396 (June 2016)</p> <p>Trametinib in combination with dabrafenib is recommended, within its marketing authorisation, as another option for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation only when the company provides trametinib and dabrafenib with the discounts agreed in the patient access schemes.</p>																		
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>The NICE costing template assumes that take up of this service will phase in over several years.</p> <table border="1" data-bbox="245 1066 1445 1321"> <thead> <tr> <th colspan="6" data-bbox="245 1066 1445 1214">Estimated number of people in Northern Ireland having trametinib with dabrafenib</th> </tr> <tr> <th data-bbox="245 1214 715 1249"></th> <th data-bbox="715 1214 858 1249">2016/17</th> <th data-bbox="858 1214 1005 1249">2017/18</th> <th data-bbox="1005 1214 1150 1249">2018/19</th> <th data-bbox="1150 1214 1295 1249">2019/20</th> <th data-bbox="1295 1214 1445 1249">2020/21</th> </tr> </thead> <tbody> <tr> <td data-bbox="245 1249 715 1321">Population having trametinib with dabrafenib each year</td> <td data-bbox="715 1249 858 1321">5</td> <td data-bbox="858 1249 1005 1321">14</td> <td data-bbox="1005 1249 1150 1321">21</td> <td data-bbox="1150 1249 1295 1321">28</td> <td data-bbox="1295 1249 1445 1321">35</td> </tr> </tbody> </table> <p>However 13 cases have been approved to date in 2016/17, so it likely that approximately 35 will be treated in year.</p>	Estimated number of people in Northern Ireland having trametinib with dabrafenib							2016/17	2017/18	2018/19	2019/20	2020/21	Population having trametinib with dabrafenib each year	5	14	21	28	35
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4	<p>Patient Access Scheme availability</p> <p>The company has agreed patient access schemes with the Department of Health. These schemes provide simple discounts to the list prices of trametinib and dabrafenib with the discounts applied at the point of purchase or invoice. The levels of the discounts are commercial in confidence.</p>																		
5	<p>Costs (before PAS if applicable)</p>																		
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The acquisition cost of trametinib is £1,120 per pack of 2mg tablets (7 tablets per pack). The recommended dose of trametinib, in combination with dabrafenib, is 2mg once daily. Hence the annual cost of treatment with trametinib in this setting is £58,400.</p> <p>The cost of dabrafenib is £1,400 per pack of 75mg tablets (28 tablets per pack).</p>																		

	The recommended dose of dabrafenib, when used in combination with trametinib, is 150 mg twice daily. The annual cost of treatment with dabrafenib in this setting is £73,000
5.2	Infrastructure costs per patient per annum Any additional infrastructure costs associated with the introduction of new cancer therapies will be included as part of the routine commissioning process.
5.3	Current in year costs In year gross costs before PAS are estimated at £480k for year 1 if 35 patients are treated
5.4	Recurrent overall costs per annum (<i>including additional costs</i>) <u>Before</u> application of any PAS discounts for trametinib and dabrafenib (and also for alternative treatments): According to the Resource Impact Template that accompanies TA396, the net resource impact will be £969,330 annually when 35 patients are being treated.
5.5	Opportunities for cost savings and how these will be secured Cost savings are not anticipated.
6	Expected implementation period There is no impediment to immediate implementation for new patients.
7	Commissioning arrangements 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 regime.
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.

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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.