

1.	<p><b>Treatment &amp; Condition</b></p> <p>Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA544 (October 2018)</p> <p>Dabrafenib (Tafinlar<sup>®</sup>) with trametinib (Mekinist<sup>®</sup>) is recommended, within its marketing authorisation, as an option for the adjuvant treatment of resected stage III BRAF V600 mutation-positive melanoma in adults. It is recommended only if the company provides dabrafenib and trametinib with the discounts agreed in the commercial arrangements.</p>
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>According to the Resource Impact Template that accompanies NICE TA544, it is expected that 19 people in Northern Ireland will take up treatment annually in line with this guidance.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p>(<u>Yes/No</u>)</p> <p>The company (Novartis Pharmaceuticals) has a commercial arrangement for each drug. This makes dabrafenib with trametinib available to the NHS with a discount. The size of the discount is commercial in confidence.</p>
5.	<p><b>Infrastructure Requirements</b></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>
6.	<p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p><b>Commissioning arrangements</b></p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, 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.	<p><b>Monitoring arrangements</b></p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p>

	<p>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.</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>
<b>9.</b>	<p><b>DoH (NI) Legislative/Policy Caveats</b></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. 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> <p>The <i>Rural Needs Act (NI) 2016</i> has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.</p>