

1.	<p>Treatment & Condition</p> <p>Ceritinib for untreated ALK-positive non-small-cell lung cancer</p>																								
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA500 (January 2018)</p> <p>Ceritinib is recommended, within its marketing authorisation, as an option for untreated anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer in adults, only if the company provides it with the discount agreed in the patient access scheme.</p>																								
3.	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>According to the Resource Impact Template that accompanies NICE TA500, the numbers of people expected to take up treated with ceritinib is as follows:</p> <table border="1" data-bbox="260 992 1444 1167"> <thead> <tr> <th></th> <th>2017/18</th> <th>2018/19</th> <th>2019/2020</th> <th>2020/21</th> <th>2021/22</th> </tr> </thead> <tbody> <tr> <td>People starting treatment</td> <td>1</td> <td>8</td> <td>11</td> <td>12</td> <td>14</td> </tr> <tr> <td>People continuing treatment from previous year</td> <td>0</td> <td>1</td> <td>8</td> <td>12</td> <td>14</td> </tr> <tr> <td>Total</td> <td>1</td> <td>9</td> <td>18</td> <td>24</td> <td>28</td> </tr> </tbody> </table>		2017/18	2018/19	2019/2020	2020/21	2021/22	People starting treatment	1	8	11	12	14	People continuing treatment from previous year	0	1	8	12	14	Total	1	9	18	24	28
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4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Novartis) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of ceritinib, with the discount applied at the point of purchase or invoice. The level of the discount is 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>Ceritinib (Zykadia[®]) is given at a dose of 750mg once daily. The summary of product characteristics recommends that treatment should continue as long as clinical benefit is observed.</p> <p>At the list price, a 30 day supply of ceritinib (150 capsules) costs £4,923 (excluding VAT). Hence the cost per patient per annum is £59,902</p>																								
5.2	<p>Infrastructure costs 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>																								

6.	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p>Commissioning arrangements</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>Monitoring arrangements</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>
9.	<p>DoH (NI) 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. 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>