

1.	<p>Treatment & Condition</p> <p>Lorlatinib for previously treated ALK-positive advanced non-small-cell lung cancer</p>																														
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA628 (May 2020)</p> <p>Lorlatinib is recommended, within its marketing authorisation, as an option for treating anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC) in adults whose disease has progressed after:</p> <ul style="list-style-type: none"> • alectinib or ceritinib as the first ALK tyrosine kinase inhibitor or • crizotinib and at least 1 other ALK tyrosine kinase inhibitor. <p>It is recommended only if the company provides lorlatinib according to the commercial arrangement.</p>																														
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>According to the Resource Impact Statement that accompanies NICE TA628, the following patient numbers are expected in Northern Ireland:</p> <table border="1" data-bbox="260 1146 1444 1451"> <thead> <tr> <th colspan="6">Estimated number of people in Northern Ireland receiving lorlatinib</th> </tr> <tr> <th></th> <th>2020/21</th> <th>2021/22</th> <th>2022/23</th> <th>2023/24</th> <th>2024/25</th> </tr> </thead> <tbody> <tr> <td>People starting lorlatinib each year</td> <td>3</td> <td>4</td> <td>5</td> <td>6</td> <td>6</td> </tr> <tr> <td>People continuing lorlatinib from previous year</td> <td></td> <td>3</td> <td>4</td> <td>5</td> <td>6</td> </tr> <tr> <td>Total people receiving lorlatinib</td> <td>3</td> <td>7</td> <td>9</td> <td>11</td> <td>12</td> </tr> </tbody> </table>	Estimated number of people in Northern Ireland receiving lorlatinib							2020/21	2021/22	2022/23	2023/24	2024/25	People starting lorlatinib each year	3	4	5	6	6	People continuing lorlatinib from previous year		3	4	5	6	Total people receiving lorlatinib	3	7	9	11	12
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4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Pfizer) has a commercial arrangement. This makes lorlatinib available to the NHS with a discount. The size of the discount is commercial in confidence.</p>																														
5.	<p>Infrastructure Requirements</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>																														

<p>7.</p>	<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>
<p>8.</p>	<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>
<p>9.</p>	<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> <p>The Rural Needs Act NI 2016 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>