

1.	<p>Treatment & Condition</p> <p>Abemaciclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer.</p>																								
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA563 (February 2019)</p> <p>Abemaciclib (Verzenios[®]) with an aromatase inhibitor is recommended, within its marketing authorisation, as an option for treating locally advanced or metastatic, hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer as first endocrine-based therapy in adults. Abemaciclib is recommended only if the company provides it 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 Template that accompanies this technology appraisal, numbers of patients expected to be treated with abemaciclib in Northern Ireland are as follows:</p> <table border="1" data-bbox="261 1104 1441 1317"> <thead> <tr> <th>Year</th> <th>2019/20</th> <th>2020/21</th> <th>2021/22</th> <th>2022/23</th> <th>2023/24</th> </tr> </thead> <tbody> <tr> <td>Number of people beginning treatment</td> <td>24</td> <td>41</td> <td>65</td> <td>65</td> <td>65</td> </tr> <tr> <td>Number of people continuing treatment from prior years</td> <td>0</td> <td>24</td> <td>48</td> <td>76</td> <td>76</td> </tr> <tr> <td>Total number treated per year</td> <td>24</td> <td>65</td> <td>113</td> <td>141</td> <td>141</td> </tr> </tbody> </table>	Year	2019/20	2020/21	2021/22	2022/23	2023/24	Number of people beginning treatment	24	41	65	65	65	Number of people continuing treatment from prior years	0	24	48	76	76	Total number treated per year	24	65	113	141	141
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4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Eli Lilly) has a commercial arrangement. This makes abemaciclib 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>