

1.	<p>Treatment & Condition</p> <p>Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA579 (May 2019)</p> <p>Abemaciclib (Verzenios[®]) with fulvestrant is recommended for use within the Cancer Drugs Fund as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in people who have had endocrine therapy only if:</p> <ul style="list-style-type: none"> • exemestane plus everolimus would be the most appropriate alternative and • the conditions in the managed access agreement for abemaciclib with fulvestrant are followed.
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>By extrapolation for the NICE Resource Impact Statement that accompanies NICE TA579, it is estimated that up to 99 people per year in Northern Ireland with hormone receptor-positive, HER2-negative advanced breast cancer after treatment with endocrine therapy will be eligible for treatment with abemaciclib with fulvestrant in line with this guidance.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Eli Lilly) has a managed access agreement, which includes a commercial arrangement, for abemaciclib. The size of the discount is commercial in confidence.</p> <p>HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the managed access agreement.</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>