

1.	<p>Treatment & Condition</p> <p>Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer.</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA593 (August 2019)</p> <p>Ribociclib (Kisqali[®]) 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 previous endocrine therapy only if:</p> <ul style="list-style-type: none"> • exemestane plus everolimus is the most appropriate alternative to a cyclin-dependent kinase 4 and 6 (CDK 4/6) inhibitor and • the conditions in the managed access agreement for ribociclib with fulvestrant are followed.
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>NICE has estimated that up to 100 people per year in Northern Ireland with hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer in people who have had previous endocrine therapy will be eligible for treatment with ribociclib with fulvestrant. However, it is the view of the local service that this number is an overestimation and the number may be more in the region of 50 patients per annum.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Novartis) has a managed access agreement, which includes a commercial arrangement, for ribociclib. The financial terms of the agreement are 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>

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 for as long as NICE indicates that funding via the Cancer Drugs Fund is appropriate.</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> <p>Numbers of patients who received or are receiving treatment by the HSC Board and reported to the Department of Health.</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> <p>The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as galling within the scope of the act.</p>