HSCB Service Notification for the managed entry of new medicines and technologies

1.	**Treatment & Condition** Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology appraisal guidance (TA687), Published: 31 March 2021 www.nice.org.uk/guidance/ta687 Ribociclib plus fulvestrant is recommended as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer in adults who have had previous endocrine therapy only if: • exemestane plus everolimus is the most appropriate alternative to a cyclin-dependent kinase 4 and 6 (CDK 4/6) inhibitor, and • the company provides ribociclib according to the commercial arrangement
3.	**Number of people in Northern Ireland expected to take up service/therapy** Ribociclib plus fulvestrant was recommended for use in the Cancer Drugs Fund (CDF; TA593). The uptake of ribociclib plus fulvestrant is not expected to change significantly when it moves into routine commissioning. Referring to NICE TA593 it was estimated that up to 100 people per year in Northern Ireland will be expected to take up this therapy.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Novartis) has a simple discount patient access scheme for ribociclib. This makes ribociclib available to the NHS with a discount. The size of the discount is commercial in confidence. HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the patient access scheme.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements**

	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.
8.	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. 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. 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.
9.	**DoH (NI) Legislative/Policy Caveats** 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.