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

1.	**Treatment & Condition** Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor positive, HER2-negative, locally advanced or metastatic breast cancer
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA496 (December 2017) Ribociclib (Kisqali®) with an aromatase inhibitor, is recommended within its marketing authorisation, as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy in adults. Ribociclib is recommended only if the company provides it with the discount agreed in the patient access scheme.
3.	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* According to the Resource Impact Template that accompanies TA496, it is expected that 31 people in Northern Ireland will be treated with ribociclib each year.
4.	**Patient Access Scheme Availability** **(<u>Yes</u>/**No**)** The company (Novartis) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of ribociclib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.
5.	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The recommended dose of ribociclib is 600mg, taken orally, once daily for 21 consecutive days, followed by 7 days off treatment (28-day cycle). Treatment should be continued as long as the patient is having clinical benefit from therapy or until unacceptable toxicity occurs. Ribociclib costs £2,950 for a 63-tablet pack of 200mg tablets (excluding VAT) at the list price. Hence the cost of treatment per patient with ribociclib, at the list price and recommended dosage is: • £2,950 per cycle, or • £38,350 per annum (assuming 13 cycles are given per annum)

5.2	**Infrastructure costs Per annum** 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 for a period of 12 months. After this time, 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.