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

Health and Social Care Board

1	**Treatment & Condition** Everolimus with exemestane for treating advanced breast cancer after endocrine therapy.
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal Guidance (TA421) December 2016 Everolimus, in combination with exemestane, is recommended within its marketing authorisation, as an option for treating advanced human epidermal growth factor receptor 2 (HER2)-negative, hormone-receptor-positive breast cancer in postmenopausal women without symptomatic visceral disease that has recurred or progressed after a non-steroidal aromatase inhibitor. Everolimus 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)* By extrapolation from the Resource Impact Statement that accompanies TA421, it is estimated that 20 women per year in Northern Ireland will have everolimus for this indication.
4.	**Patient Access Scheme Availability** **(Yes/No)** The company (Novartis Pharmaceuticals) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of everolimus 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)** Everolimus (Afinitor®) has a UK marketing authorisation for the 'treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a nonsteroidal aromatase inhibitor'. Everolimus is administered orally. The recommended dosage is 10 mg once daily and treatment should continue as long as patients benefit clinically, or until they have unacceptable adverse reactions. Adverse reactions that are severe and/or intolerable may be managed by reducing the dosage to 5 mg daily or temporarily stopping treatment then reintroducing it at 5 mg daily.

	The list price for a pack (30 tablets per pack) of 10mg tablets and 5mg tablets is £2,673 and £2,250 respectively (excluding VAT). Given that NICE has estimated that the average duration of treatment is 5.5months, the cost of treatment with everolimus is between £12,375 and £14,701 per patient at list price.
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 regime.
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.