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

Health and Social Care Board

1	**Treatment & Condition** Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal Guidance (TA424) December 2016 Pertuzumab, in combination with trastuzumab and chemotherapy, is recommended, within its marketing authorisation, as an option for the neoadjuvant treatment of adults with human epidermal growth factor receptor 2 (HER2)-positive breast cancer; that is, in patients with HER2-positive, locally advanced, inflammatory or early-stage breast cancer at high risk of recurrence. It is recommended only if the company provides pertuzumab 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 TA424, there will be 1,125 people in Northern Ireland treated with pertuzumab and trastuzumab (in line with TA424). However, it is the view of local clinicians that of the 1330 breast cancer patients diagnosed per annum approximately15% will be Her2 positive of which approximately two thirds may have neoadjuvant treatment. It is therefore estimated that around 130 patients would be eligible for treatment with pertuzumab.
4.	**Patient Access Scheme Availability** **(<u>Yes</u>/**No**)** The company (Roche) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of pertuzumab, 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)** Pertuzumab (Perjeta®) has a marketing authorisation in the UK 'in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer at high risk of recurrence'. The recommended dosage of pertuzumab is an initial loading dose of 840 mg

	administered as a 60 minute intravenous infusion, followed by a maintenance dose of 420 mg administered over a period of 30 to 60 minutes, every 3 weeks for 3 to 6 cycles. Pertuzumab costs £2,395 per 420-mg vial (excluding VAT). Hence, the cost per patient for a full course of treatment at the list price will be between £11,975 and £19,160 depending on the number of cycles given
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.