

1.	<p>Treatment & Condition</p> <p>Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA509 (March 2018)</p> <p>Pertuzumab, in combination with trastuzumab and docetaxel, is recommended, within its marketing authorisation, for treating HER2-positive metastatic or locally recurrent unresectable breast cancer, in adults who have not had previous anti-HER2 therapy or chemotherapy for their metastatic disease, only if the company provides pertuzumab within the agreed commercial access arrangement.</p>
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>According to the Resource Impact Template that accompanies NICE TA509, it is expected that 28 patients per annum will take up treatment with pertuzumab in line with this TA.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Roche Products) has agreed a commercial access arrangement for pertuzumab. The commercial access arrangement replaces the patient access scheme agreed with the Department of Health for pertuzumab. The details of this commercial access arrangement are commercial in confidence.</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. 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.</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>
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>