

1.	<p>Treatment & Condition</p> <p>Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2 positive early stage breast cancer after adjuvant trastuzumab.</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA612 (November 2019).</p> <p>Neratinib (Nerlynx[®]) is recommended as an option for the extended adjuvant treatment of hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-positive early stage breast cancer in adults who completed adjuvant trastuzumab-based therapy less than 1 year ago only if:</p> <ul style="list-style-type: none"> • trastuzumab is the only HER2-directed adjuvant treatment they have had, and • if they had neoadjuvant chemotherapy-based regimens, they still had residual invasive disease in the breast or axilla following the neoadjuvant treatment, and • the company provides neratinib according to the commercial arrangement.
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 TA612, it is estimated that 13 people in Northern Ireland will be eligible for treatment with neratinib in line with this Technology Appraisal.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Pierre Fabre) has a commercial arrangement. This makes neratinib available to the NHS with a discount. The size of the discount is 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> <p>The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act.</p>