

1.	<p>Treatment & Condition</p> <p>Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA458 (July 2017)</p> <p>Trastuzumab emtansine is recommended, within its marketing authorisation, as an option for treating human epidermal growth factor receptor 2 (HER2)-positive, unresectable, locally advanced or metastatic breast cancer in adults who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy. Trastuzumab emtansine is recommended only if the company provides it in line with the commercial access agreement.</p>
3.	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>According to the Resource Impact Template that accompanies TA458 it is estimated that 24 patients per annum would be eligible for treatment with trastuzumab emtansine in Northern Ireland</p>
4.	<p>Patient Access Scheme Availability</p> <p>Yes</p> <p>The pricing arrangement considered during guidance development was one in which the company (Roche) had agreed a complex patient access scheme with the Department of Health. At the end of the appraisal process, the patient access scheme was replaced with a commercial access agreement between Roche and NHS England. The commercial access agreement provides similar reductions in the total costs of treatment to the latest patient access scheme offer, and a simpler operational approach. The details of the agreement are commercial in confidence.</p>
5.	<p>Costs (before PAS if applicable)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Trastuzumab emtansine is administered as an intravenous infusion. The recommended dose is 3.6 mg/kg bodyweight every 3 weeks (21-day cycle). Patients should have treatment until the disease progresses or unacceptable toxicity occurs.</p> <p>The list price for trastuzumab emtansine is £1,641 for a 100mg vial and</p>

	<p>£2,626 for a 160mg vial (excluding VAT). The company estimates that the average cost of a course of treatment is £91,614, using the list price, and based on a 3-weekly dose of 3.6mg/kg, a patient weight of 70.1kg and an average length of treatment of 14.5 months.</p>
5.2	<p>Infrastructure costs Per annum</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 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.</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>