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

Health and Social Care Board

1	**Treatment & Condition** Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy
2	**Associated appraisal body** *(NICE/SMC/Other)* **& Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE Technology Appraisal Guidance (TA374) December 2015. Review of TA162 and TA175) Erlotinib (Tarceva ®) is recommended as an option for treating locally advanced or metastatic non-small-cell lung cancer (NSCLC) that has progressed in people who have had non-targeted chemotherapy because of delayed confirmation that their tumour is epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive, only if the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE TA258. Erlotinib is recommended as an option for treating locally advanced or metastatic NSCLC that has progressed after non-targeted chemotherapy in people with tumours of unknown EGFR-TK mutation status, only if: • the result of an EGFR-TK mutation diagnostic test is unobtainable because of an inadequate tissue sample or poor-quality DNA and • the treating clinician considers that the tumour is very likely to be EGFR-TK mutation-positive and • the person's disease responds to the first 2 cycles of treatment with erlotinib and the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE TA258 Erlotinib is not recommended for treating locally advanced or metastatic NSCLC that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-negative. Gefitinib (Iressa®) is not recommended for treating locally advanced or metastatic NSCLC that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-positive.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* Erlotinib is already in use for the cohort of patients recommended in this TA.
4	**Patient Access Scheme availability** Roche Products (the manufacturer of erlotinib) has agreed a patient access scheme with the Department of Health, with a simple discount applied at the point of purchase or invoice. The level of discount is commercial in confidence.

5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Erlotinib is given orally at a recommended dosage of 150 mg once daily. The cost for a 30-tablet pack of 150-mg tablets is £1631.53. Therefore the annual drug cost per patient is £19,850.00 Roche Products has agreed a patient access scheme with the Department of Health, with a simple discount applied at the point of purchase or invoice. The level of discount is commercial in confidence.
5.2	**Infrastructure costs per patient per annum** As Erlotinib is already in use for the cohort of patients recommended in this TA there should be no additional service impact with the implementation of NICE TA374.
5.3	**Current in year costs** Not significant as erlotinib is already in use.
5.4	**Recurrent overall costs per annum** *(including additional costs)* According to the Resource Impact Report that accompanies TA373, it is unlikely that the guidance will result in a significant change in resource use in the NHS. The updated recommendations for erlotinib reduce the population eligible for treatment. People with EGFR-TK mutation-negative tumours will no longer be eligible for treatment with erlotinib under the new guidance, but will continue to be eligible for treatment with docetaxel as recommended in the NICE Clinical Guideline on the diagnosis and treatment of lung cancer. It is assumed the majority of these people currently receive docetaxel.
5.5	**Opportunities for cost savings and how these will be secured** Cost savings are not anticipated
6	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7	**Commissioning arrangements** This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team as part of the routine commissioning process.
8	**Monitoring arrangements** 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	**DHSSPS 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.