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

1	**Treatment & Condition** Afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer
2	**Associated appraisal body** *(NICE/SMC/Other)* ***&*** **Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE Technology Appraisal Guidance 310 (April 2014) Afatinib is recommended as an option, within its marketing authorisation, for treating adults with locally advanced or metastatic non-small-cell lung cancer only if: • the tumour tests positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation **and** • the person has not previously had an EGFR-TK inhibitor **and** • the manufacturer provides afatinib 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)* Approximately 11 to 17% of NSCLC patients have tumours which are EGFR mutation positive (23 patients per year in Northern Ireland in the advanced or metastatic setting). The current standard of care for these patients is Gefitinib which is an oral tyrosine kinase inhibitor and Afatanib is another oral EGFR tyrosine kinase inhibitor. Afatanib would be considered as an alternative to Gefitinib for patients with advanced or metastatic NSCLC harbouring an activating EGFR mutation.
4	**Patient Access Scheme availability** The manufacturer of afatinib has agreed a patient access scheme with the Department of Health in which a confidential discount is applied at the point of purchase or invoice.
5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The NHS list price is £2023.28 per pack of 28 tablets (20 mg, 30 mg, 40 mg or 50 mg). The NHS list price per course of treatment is expected to be around £22,000 per patient, based on a progression-free survival of 11 months. NICE suggest that Afatanib is cost neutral to Gefitinib which is already recurrently funded in NI for both drug acquisition costs and the associated EGFR testing.

5.2	**Infrastructure costs per patient per annum** Afatinib is given orally as a once daily tablet. Patients will receive their supply from a hospital pharmacy. As Afatinib will be an alternative to Gefitinib, there should be no additional service Impact to introduce this new regime.
5.3	**Current in year costs** Afatinib is considered to be a reasonable alternative treatment option compared with erlotinib and gefitinib. Treatment with afatinib is not expected to have a significantly different cost to that of current standard treatment options. The gross price per patient is £22,000. Afatinib is being provided at a price after PAS which is comparable to erlotinib and gefitinib, ensuring there is no additional cost to introduce.
5.4	**Recurrent overall costs per annum** *(including additional costs)* Afatinib is considered to be a reasonable alternative treatment option compared with erlotinib and gefitinib. Treatment with afatinib is not expected to have a significantly different cost to that of current standard treatment options. The gross price per patient is £22,000. Afatinib is being provided at a price after PAS which is comparable to erlotinib and gefitinib, ensuring there is no additional cost to introduce.
5.5	**Opportunities for cost savings and how these will be secured** Implementation of NICE TA310 is unlikely to result in any cost savings. Treatment with erlotinib or gefitinib is standard practice for most people presenting with EGFR mutation-positive locally advanced or metastatic NSCLC. Afatinib is considered to be a reasonable alternative treatment option compared with erlotinib and gefitinib. Treatment with afatinib is not expected to have a significantly different cost to that of current standard treatment options. Afatinib is an additional treatment option alongside current standard treatment options erlotinib and gefitinib which are both available with a patient access scheme.
6	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7	**Commissioning arrangements** This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team on a CPC basis for use in the cancer centre and cancer units.

8	**Monitoring arrangements** The HSCB IFR process will generate quarterly reports on the number of Cost Per Case applications which will be reviewed formally by the Specialist Services Commissioning Team on a quarterly basis. HSCB currently 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.