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

Health and Social Care Board

1	**Treatment & Condition** Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal Guidance (TA395) June 2016 Ceritinib is recommended, within its marketing authorisation, as an option for treating advanced anaplastic lymphoma kinase positive non‑small‑cell lung cancer in adults who have previously had crizotinib. The drug is recommended only if the company provides it 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)* It is unlikely that the guidance will result in a significant change in resource use in Northern Ireland because the population having had previous treatment with crizotinib size is low. From information collected via the IFR process it is anticipated that it is likely that 1 – 2 patients per annum would be eligible for treatment with ceritinib.
4	**Patient Access Scheme availability** Ceritinib is taken orally, once daily. The recommended dose is 750 mg (5 × 150mg capsules). The NHS list price is £4,923 for a 30 day supply. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of ceritinib at the point of purchase or invoice. The level of the discount is commercial in confidence.
5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Ceritinib (Zykadia®) has a marketing authorisation in the UK for treating adult patients with anaplastic lymphoma kinase (ALK) positive advanced non‑small‑cell lung cancer (NSCLC) previously treated with crizotinib. Ceritinib is an ALK inhibitor. Ceritinib is taken orally, once daily. The recommended dose is 750 mg (5 × 150mg capsules). The NHS list price is £4,923 for a 30 day supply. In clinical trials, patients took ceritinib for an average of 8.6months. Hence the average cost of treatment per patient is £42,341.

5.2	**Infrastructure costs per patient per annum** Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process.
5.3	**Current in year costs** If 2 patients present, in year costs (before PAS) will be approximately £85,000
5.4	**Recurrent overall costs per annum** *(including additional costs)* It is unlikely that the guidance will result in a significant change in resource use in Northern Ireland because the population having had previous treatment with crizotinib size is low. Crizotinib is now NICE approved for first-line use and it is anticipated that this will result in an increase in patients receiving it but the numbers are likely to be less than 5 each year. Recurrent costs (before PAS) for 2 patients per annum will be approximately £85,000.
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 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. Given that first-line crizotinib has recently gained NICE approval, the numbers of patients receiving ceritinib may not reach steady state until year 2.
8	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. 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.