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

Health and Social Care Board

1.	**Treatment & Condition** Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA451 (June 2017) Ponatinib is recommended, within its marketing authorisation, as an option for treating chronic-, accelerated- or blast-phase **chronic myeloid leukae**mia in adults when: • the disease is resistant to dasatinib or nilotinib or • they cannot tolerate dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate or • the T315I gene mutation is present. Ponatinib is recommended, within its marketing authorisation, as an option for treating Philadelphia-chromosome-positive **acute lymphoblastic leukaemia** in adults when: • the disease is resistant to dasatinib or • they cannot tolerate dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate or • the T315I gene mutation is present. Ponatinib is recommended only if the company provides the drug 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)* NICE states that as this represents a further treatment option for this patient population the implementation of TA451 will not change current clinical practice and patient numbers should not change significantly from the current baseline.
4.	**Patient Access Scheme Availability** **(<u>Yes</u>/**No**)** The company (Incyte Corporation) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of ponatinib with the discount applied 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)** The recommended starting dose is 45mg of ponatinib once daily. For the standard dose of 45 mg once daily, a 45mg film-coated tablet is available at a cost of £5,050 for 30 x 45mg tablets. Treatment should be continued as long as the patient does not show evidence of disease progression or unacceptable toxicity. Dose levels and dose adjustments are determined by time on treatment, treatment response, and adverse reactions to treatment. Hence the drug cost, per patient per annum (assuming a dose of 45mg daily) is £61,442 (list price).
5.2	**Infrastructure costs 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.
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements** 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.
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.	**DoH (NI) 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.