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

Health and Social Care Board

1.	**Treatment & Condition** Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA429 (January 2017) Ibrutinib alone is recommended within its marketing authorisation as an option for treating chronic lymphocytic leukaemia in adults: • who have had at least 1 prior therapy, or • who have a 17p deletion or TP53 mutation, and in whom chemo-immunotherapy is unsuitable, and • only when the company provides ibrutinib 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)* The number of people in Northern Ireland estimated to have ibrutinib each year for this indication (based on the NICE Resource Impact template that accompanies TA429) is 23. This estimate is supported by the local clinicians.
4.	**Patient Access Scheme Availability** **(<u>Yes</u>/**No**)** The company (Janssen) has agreed a patient access scheme with the Department of Health. 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)** Ibrutinib is administered orally at a daily dose of 420 mg (3 tablets) until disease progression or intolerance. The list price for a single tablet of ibrutinib (140mg) is £51.10 (excluding VAT). The cost of a year's course of ibrutinib treatment is £55,954.50 (excluding VAT). The company has agreed a patient access scheme with the Department of Health. The level of the discount is commercial in confidence.
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.