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

1.	**Treatment & Condition** Venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA663 (December 2020) Venetoclax plus obinutuzumab is recommended as an option for untreated chronic lymphocytic leukaemia (CLL) in adults, only if: • there is a 17p deletion or TP53 mutation, or • there is no 17p deletion or TP53 mutation, and fludarabine plus cyclophosphamide and rituximab (FCR), or bendamustine plus rituximab (BR), is unsuitable, and • the companies provide the drugs according to the commercial arrangements. Venetoclax plus obinutuzumab is recommended for use within the Cancer Drugs Fund as an option for untreated CLL in adults, only if: • there is no 17p deletion or TP53 mutation, and FCR or BR is suitable, and • the conditions in the managed access agreement for venetoclax plus obinutuzumab are followed.
3.	**Number of people in Northern Ireland expected to take up service/therapy** By extrapolation from the Resource Impact Report that accompanies NICE TA663, it is estimated that, in Northern Ireland, 36 people will have venetoclax with obinutuzumab from 2022/23 onwards. This is approximately 1 to 2 people with a 17p deletion or TP53 mutation and 35 people with no 17p deletion or TP53 mutation.
4.	**Patient Access Scheme Availability** (Yes/No) The companies (AbbVie and Roche) have managed access arrangements. These make venetoclax and obinutuzumab available to the NHS with a discount. The size of the discounts is commercial in confidence. HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the commercial and managed access arrangements.
5.	**Infrastructure Requirements** 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. Thereafter, 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 for the non-CDF indication
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. Numbers of patients who received or are receiving treatment under the CDF indication will be monitored by the HSC Board and reported to the Department of Health.
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.