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

1	**Treatment & Condition** *(Title)* Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia Ofatumumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia
2	**Associated appraisal body** *(NICE/SMC/Other)* **& Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE technology appraisal guidance 343 and 344 (June 2015) Obinutuzumab, in combination with chlorambucil, is recommended as an option for adults with untreated chronic lymphocytic leukaemia who have comorbidities that make full-dose fludarabine-based therapy unsuitable for them, only if: • bendamustine-based therapy is not suitable and • the company provides obinutuzumab with the discount agreed in the patient access scheme. Ofatumumab in combination with chlorambucil is recommended as an option for untreated chronic lymphocytic leukaemia only if: • the person is ineligible for fludarabine-based therapy and • bendamustine is not suitable and • the company provides ofatumumab 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)* Obinutuzumab (NICE TA343) is being introduced alongside ofatumumab (NICE TA344). Both these agents are used in a similar patient group. Patients will be treated with one or other of these. The NICE costing statement accompanying this service notification suggests that the population eligible for treatment is estimated to be 550 per year in England by year 5. Based on a pro rata calculation from the Costing Statement that accompanies TA343 and TA344, the population eligible for treatment is estimated to be approximately 16 people per year in Northern Ireland by year 5 (approximately 3 patients per year).
4	**Patient Access Scheme availability** The manufacturer of obinutuzumab has agreed a patient access scheme with the Department of Health, in which the acquisition cost of obinutuzumab will be discounted. The size 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 price of obinutuzumab is £3312 per 1000-mg vial. The company has stated that a course of treatment costs £26,496 (£9936 for cycle 1 and £3312 for cycles 2–6). The recommended dosage is 1000 mg administered over days 1 and 2, 1000 mg on day 8 and 1000 mg on day 15 of treatment cycle 1, followed by 1000 mg on day 1 of treatment cycles 2–6. The company has agreed a patient access scheme with the Department of Health that makes obinutuzumab available with a discount. The size of the discount is commercial in confidence Ofatumumab is priced at £182 for a 100-mg vial and £1,820 for a 1000-mg vial. Assuming 6 cycles and no drug wastage, the mean cost of a treatment course for ofatumumab is £11,466 for 6300 mg. The company has agreed a patient access scheme with the Department of Health that makes ofatumumab available with a discount. The size of the discount is commercial in confidence.
5.2	**Infrastructure costs per patient per annum** There will be an opportunity for infrastructure issues to be reviewed on an annual basis.
5.3	**Current in year costs** The gross in year cost based on the costing statement for both TA343 and TA344 for N. Ireland is estimated to be around £30k
5.4	**Recurrent overall costs per annum** *(including additional costs)* The gross recurrent cost at year 5, based on the costing statement for both TA343 and TA344 for N. Ireland is estimated to be £231k.
5.5	**Opportunities for cost savings and how these will be secured** It is unlikely that implementation of NICE TA343 will result in any cost-savings. It can however be noted that rituximab for 1st line CLL is recurrently funded for 32 patients across the region. This regime will be an option at the same point of the pathway as that of Rituximab, and therefore, this may result in less patients receiving Rituximab. The choice of drug to be used will be at clinical discretion, and therefore the impact of the introduction of this regime on the use of rituximab is currently unknown. These savings are unlikely to be cash releasing, rather the decrease in expenditure against rituximab is likely to offset increases in expenditure in other regimes and be considered as part of the total overall cancer drug budget available to the Trust. It is unlikely that implementation of NICE TA344 will result in any cost-savings.
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. HSCB will now move to identifying recurrent funding to support this regime, however due to the small number of new patients per year and the inability to predict whether these patients will present at the centre or one of the units, this regime will continue on a cost per case basis for a 12 month period to allow for a trend to be identified.
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.