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

Health and Social Care Board

1	**Treatment & Condition** *(Title)* Idelalisib (Zydelig®) for treating chronic lymphocytic leukaemia.
2	**Associated appraisal body** *(NICE/SMC/Other)* **&** **Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE Technology Appraisal Guidance 359 (October 2015) Idelalisib, in combination with rituximab, is recommended: • For untreated chronic lymphocytic leukaemia in adults with a 17p deletion or TP53 mutation or • For chronic lymphocytic leukaemia in adults when the disease has been treated but has relapsed within 24 months Idelalisib is recommended only if the company provides the drug with the discount agreed in the simple discount agreement.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* According to the Costing Template that accompanies NICE TA359, the number of people in Northern Ireland expected to take up treatment under this Technology Appraisal is as follows: • For untreated chronic lymphocytic leukaemia in adults with a 17p deletion or TP53 mutation = **10 patients** • For chronic lymphocytic leukaemia in adults with refractory disease whose disease has failed treatment or has relapsed within 6 months = **8 patients** • For chronic lymphocytic leukaemia in adults when the disease has been treated but has relapsed within 6 to 24 months = **12 patients**
4	**Patient Access Scheme availability** The company has a simple discount agreement that provides a discount to the list price of idelalisib. 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 dose and schedule is 150mg taken orally, twice daily. Treatment is continued until disease progression or unacceptable toxicity. The NICE guidance references median progression free survival for idelalisib plus rituximab compared with rituximab plus placebo as 19.4 months. Therefore it could be assumed that the duration of treatment is likely to be 19-20 months. Idelalisib is priced at £3114.75 for 60 150mg tablets. The mean cost of a 1-year treatment course for

	idelalisib is £38,000. The company has a simple discount agreement that provides a discount to the list price of idelalisib. The level of the discount is commercial in confidence.
5.2	**Infrastructure costs per patient per annum** The infrastructure costs associated with the implementation of this regime will be considered as part of the regional service impact process.
5.3	**Current in year costs** The current in year costs will be covered via the cost per case arrangement.
5.4	**Recurrent overall costs per annum** *(including additional costs)* The estimated recurrent cost as per the costing template (before PAS) is £1.453m Phased in over 2016/17 and 2017/8 at £847k and £606k
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. Idelalisib will be commissioned on the following basis: • For untreated chronic lymphocytic leukaemia in adults with a 17p deletion or TP53 mutation • For chronic lymphocytic leukaemia in adults with refractory disease whose disease has failed treatment or has relapsed within 24 months 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. Idelalisib will be commissioned on the following basis: • For untreated chronic lymphocytic leukaemia in adults with a 17p deletion or TP53 mutation. • For chronic lymphocytic leukaemia in adults with refractory disease whose

	disease has failed treatment or has relapsed within 24 months 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** *(NICE guidance only)* 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.