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

Health and Social Care Board

1	**Treatment & Condition** Bosutinib for previously treated chronic myeloid leukaemia.
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance (TA401) August 2016 Bosutinib (Bosulif®) is recommended as an option, within its marketing authorisation, for chronic, accelerated and blast phase Philadelphia chromosome positive chronic myeloid leukaemia in adults, when: • they have previously had 1 or more tyrosine kinase inhibitor and • imatinib, nilotinib and dasatinib are not appropriate and • the company provides bosutinib with the discount agreed in the patient access scheme (as revised in 2016).
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* According to the Resource Impact template that accompanies TA401, the following numbers of patients are expected to be treated with bosutinib: • **1 person** for whom dasatinib is not appropriate and are treated with bosutinib as a third line TKI • **1 person** for whom third line dasatinib is unsuccessful who have bosutinib as a fourth line TKI Thus, in total it is expected that **2 people** will be treated with bosutinib annually in Northern Ireland.
4	**Patient Access Scheme availability** The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of bosutinib, 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)** Bosutinib is administered orally. The recommended dose is 500 mg once daily. The dose can be increased up to 600 mg if there has not been a complete haematological response by week 8 or a complete cytogenetic response by week 12. Bosutinib costs £3,437 for 28 × 500mg tablets and £859 for 28 × 100mg tablets. The average cost is £123 for 500 mg/day. The annual cost of bosutinib at this dose

	is £44,800 per patient. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of bosutinib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.
5.2	**Infrastructure costs per patient 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.
5.3	**Current in year costs** Bosutinib is an additional tyrosine kinase inhibitor (TKI) which provides an additional treatment option for people with Philadelphia chromosome positive CML when other TKIs are either ineffective or inappropriate. In addition, numbers of patients expected to be treated with bosutinib are very small. Hence, the recurrent overall costs per annum are expected to be negligible.
5.4	**Recurrent overall costs per annum** *(including additional costs)* Bosutinib is an additional tyrosine kinase inhibitor (TKI) which provides an additional treatment option for people with Philadelphia chromosome positive CML when other TKIs are either ineffective or inappropriate. In addition, numbers of patients expected to be treated with bosutinib are very small. Hence, the recurrent overall costs per annum are expected to be negligible.
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 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 regime.
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.