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

1.	**Treatment & Condition** Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer
2.	**Associated appraisal body *&* Summary of ruling** NICE technology Appraisal guidance TA668 (January 2021) Encorafenib plus cetuximab is recommended, within its marketing authorisation, as an option for treating BRAF V600E mutation-positive metastatic colorectal cancer in adults who have had previous systemic treatment. It is recommended only if the company provides it according to the commercial arrangements
3.	**Number of people in Northern Ireland expected to take up service/therapy** According to the Resource Impact Template that accompanies TA668, in Northern Ireland, 13 people will receive treatment with encorafenib plus cetuximab from year 2023/24 onwards once uptake has reached 90%
4.	**Patient Access Scheme Availability** (**Yes**/No) The companies Braftovi®; Pierre Fabre Ltd. (encorafenib) and Erbitux®; Merck Serono Ltd (cetuximab) have commercial arrangements for each of the drugs in place. These make encorafenib and cetuximab available to the NHS with discounts. 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 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 with 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
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.