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

1.	**Treatment & Condition** Avelumab for untreated metastatic Merkel cell carcinoma
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA691 (April 2021) Avelumab (Bavencio®) is recommended as an option for treating metastatic Merkel cell carcinoma in adults who have not had chemotherapy for metastatic disease. It is recommended only if the company provides avelumab according to the commercial arrangement. This appraisal reviews the additional evidence collected in the Cancer Drugs Fund managed access agreement for avelumab for metastatic Merkel cell carcinoma in adults who have not had chemotherapy for metastatic disease (NICE technology appraisal guidance 517). The new evidence includes data from clinical trials and from people having treatment in the NHS while this treatment was available in the Cancer Drugs Fund in England.
3.	**Number of people in Northern Ireland expected to take up service/therapy** According to the Resource Impact Statement that accompanies the NICE TA691, it is estimated, based on Cancer Drugs Fund data, that fewer than 100 people will be eligible for treatment with avelumab in England. In Northern Ireland it is therefore estimated (pro rata) that there will be **3 people eligible** for treatment with avelumab in line with this appraisal.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Merck/Pfizer) has a commercial arrangement. This makes avelumab available to the NHS with a discount. The size of the discount is commercial in confidence
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.