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

Health and Social Care Board

1.	**Treatment & Condition** Avelumab for treating metastatic Merkel cell carcinoma
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA517 (April 2018) In its Technology Appraisal guidance, NICE makes the following recommendations: 1. Avelumab is recommended as an option for treating metastatic Merkel cell carcinoma in adults, only if they have had 1 or more lines of chemotherapy for metastatic disease. 2. Avelumab is recommended for use within the Cancer Drugs Fund as an option for treating metastatic Merkel cell carcinoma in adults, only if: • they have not had chemotherapy for metastatic disease and • the conditions in the managed access agreement for avelumab are followed
3.	**Number of people in Northern Ireland expected to take up service/therapy** In treatment-experienced patients (indication 1 above) it is expected that 1 patient per year in NI would be expected to take up treatment with avelumab. In treatment-naïve patients (indication 2 above) it is expected that 3 patients per year in NI would be expected to take up treatment with avelumab.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Merck - Pfizer) has a managed access arrangement. This makes avelumab available to the NHS with a discount. The size of the discount is commercial in confidence. HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the managed access arrangement.
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 will 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 for the non-CDF indication
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. Numbers of patients who received or are receiving treatment under the CDF indication will be monitored by the HSC Board and reported to the Department of Health.
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. The *Rural Needs Act (NI) 2016* has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.