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

Health and Social Care Board

1.	**Treatment & Condition** Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma
2.	**Associated appraisal body *&* Summary of ruling** NICE technology Appraisal guidance TA661 (25 November 2020) Pembrolizumab is recommended as an option for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express PD-L1 with a combined positive score (CPS) of 1 or more. This is only if: • pembrolizumab is given as a monotherapy • pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if disease progresses, and • the company provides pembrolizumab according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** According to the Resource Impact Statement that accompanies TA 661, it is estimated that in 2020/21 approximately 2 patients will receive pembrolizumab increasing to 14 patients in 2021/22 and 25 patients from year 2022/23 onwards once uptake has reached 75%.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Merck, Sharp & Dohme) has a commercial arrangement in place. This makes pembrolizumab 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 commercial agreement.
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.