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

1.	**Treatment & Condition** Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA684. Published: 17 March 2021 www.nice.org.uk/guidance/ta684 Nivolumab (Opdivo®) is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** This guidance updates and replaces NICE technology appraisal guidance 558 on nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease which was available through the Cancer Drugs Fund. According to the Resource Impact Template that accompanies TA684, NICE estimate in Northern Ireland: • 56 people with completely resected melanoma with lymph node involvement or metastatic disease are eligible for treatment with nivolumab each year. • 10 people currently have nivolumab and this number is not expected to change when nivolumab moves into routine commissioning.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Bristol-Myers Squibb) has a commercial arrangement in place. This makes nivolumab 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 arrangement.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated 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.