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

1.	**Treatment & Condition** Nivolumab for previously treated non-squamous non-small-cell lung cancer.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA484 (November 2017). Nivolumab (Opdivo®) is recommended for use within the Cancer Drugs Fund as an option for treating locally advanced or metastatic non-squamous non-small-cell lung cancer in adults after chemotherapy, only if: • their tumours are PD‑L1 positive and • nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression, and • the conditions in the managed access agreement are followed.
3.	**Number of people in Northern Ireland expected to take up service/therapy** According to the NICE Resource Impact Statement that accompanies TA484, it is estimated that 350 people in England are eligible for treatment with nivolumab, over the course of the managed access agreement. Extrapolated to the Northern Ireland population, this equates to 12 people in Northern Ireland over the course of the managed access agreement who will take up treatment with nivolumab. In a similar SMC appraisal (1180/16), the submitting company estimated there would be 200 patients eligible for treatment with nivolumab per year. The uptake rate was estimated to be 11% in year 1 (22 patients), rising to 42% in year 5 (84 patients). Extrapolated to the Northern Ireland population, this equates to 69 patients eligible for treatment with nivolumab per year in Northern Ireland (8 patients in year 1 and 29 patients in year 5).
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Bristol-Myers Squibb) has a managed access arrangement. 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 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 on a cost-per-case (CPC) basis for as long as NICE indicates that funding via the Cancer Drugs Fund is appropriate.
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 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 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.