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

1	**Treatment & Condition** *(Title)* Pembrolizumab (Keytruda®) for advanced melanoma not previously treated with ipilimumab
2	**Associated appraisal body** *(NICE/SMC/Other)* **& Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE Technology Appraisal Guidance TA366 (November 2015) Pembrolizumab is recommended as an option for treating advanced (unresectable or metastatic) melanoma that has not been previously treated with ipilimumab, in adults, only when the company provides pembrolizumab with the discount agreed in the patient access scheme.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* According to the costing template that accompanies TA366, it is estimated that approximately 40 people in Northern Ireland would be eligible for treatment with pembrolizumab as recommended in this TA. Currently patients are prescribed Ipilimumab. We may expect that Pembrolizumab will largely replace Ipilimumab as first line for metastatic disease. As its side effect profile is more favourable it is expected to be prescribed to a larger number of patients than currently prescribed Ipilimumab. This position has been confirmed by local clinicians with an estimated volume of 40 patients per annum.
4	**Patient Access Scheme availability** The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of pembrolizumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.
5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The acquisition cost of pembrolizumab is £1315 per 50mg vial. Pembrolizumab is administered intravenously for 30 minutes at a dose of 2 mg/kg every 3 weeks until disease progression or unacceptable toxicity. Assuming an average patient weight of 77.2kg, each dose requires 4 vials (154.4 mg) and costs £5230.00. Patients receive an average of 7.2 doses at a total cost of £37,872 per patient.

5.2	**Infrastructure costs per patient per annum** As the majority of people eligible for Pembrolizumab 1st line are already receiving SACT therapy (Ipilimumab), infrastructure costs associated with implemented of this TA are expected to be very modest. However, any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process.
5.3	**Current in year costs** The current in year costs will be covered by a cost per case arrangement.
5.4	**Recurrent overall costs per annum** *(including additional costs)* The recurrent cost based on the NICE template, adjusted for local assumptions is a saving of £593k before PAS discount. Local assumptions are that little or no Ipilimumab will be used in future. This position will be monitored on an on-going basis.
5.5	**Opportunities for cost savings and how these will be secured** No net cost savings identified.
6	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7	**Commissioning arrangements** This drug will be formally commissioned by the HSCB/PHA by the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis for a period of 12 months. After this time, 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 regime.
8	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. The 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 Cancer 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	**DHSSPS Legislative/Policy Caveats *(NICE guidance only)*** 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.