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

Health and Social Care Board

1	**Treatment & Condition** Talimogene laherparepvec for treating unresectable metastatic melanoma.
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance (TA410) (September 2016) Talimogene laherparepvec is recommended, in adults, as an option for treating unresectable, regionally or distantly metastatic (Stage IIIB, IIIC or IVM1a) melanoma that has not spread to bone, brain, lung or other internal organs, only if: • treatment with systemically administered immunotherapies is not suitable and • the company provides talimogene laherparepvec 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)* Based on an extrapolation from the NICE estimation for patient numbers in England, it is anticipated that there may be 3 people annually in Northern Ireland who could be eligible for treatment with talimogene laherparepvec.
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 talimogene laherparepvec, 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)** Talimogene laherparepvec (Imlygic®) is injected directly into cutaneous, subcutaneous and nodal lesions that are visible on the skin, palpable, or detectable with ultrasound guidance. It is administered by intralesional injection at an initial dose of 1,000,000 plaque forming units (PFU) per ml, followed by doses of 100,000,000 PFU per ml at 3 weeks and then every 2 weeks. The acquisition cost of talimogene laherparepvec is £1,670 per 1 ml vial of either 1,000,000 plaque forming units (PFU) per ml or 100,000,000 PFU per ml (excluding VAT).

	<table><tr><th colspan="4">Treatment cost per patient (BEFORE PAS)</th></tr><tr><th>Treatment visit</th><th>Treatment Interval</th><th>Dose</th><th>Cost</th></tr><tr><td>Initial</td><td>-</td><td>Up to 4ml of 1,000,000 PFU/ml</td><td>Up to £6680</td></tr><tr><td>Second</td><td>3 weeks after initial treatment</td><td>Up to 4ml of 100,000,000 PFU/ml</td><td>Up to £6680</td></tr><tr><td>Third and all subsequent</td><td>2 weeks after previous treatment</td><td>Up to 4ml of 100,000,000 PFU/ml</td><td>Up to £6680</td></tr></table> In clinical trials, the mean treatment duration with of talimogene laherparepvec was 26.83 weeks. Hence the average annual cost per patient based on this treatment duration is £86,840 (at maximum dosage).
5.2	**Infrastructure costs per patient per annum** 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** Assuming 2 patients commence treatment in January 2017, the in year costs will be approximately £95,000
5.4	**Recurrent overall costs per annum** *(including additional costs)* Assuming 3 patients are treated annually, the recurrent costs will be approximately £260,000.
5.5	**Opportunities for cost savings and how these will be secured** Cost savings are not anticipated.
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 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. 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.