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

1.	**Treatment & Condition** Cetuximab for treating recurrent or metastatic squamous cell cancer of the head and neck.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal Guidance TA473 (August 2017) Cetuximab in combination with platinum-based chemotherapy is recommended as an option for treating recurrent or metastatic squamous cell cancer of the head and neck in adults only: • if the cancer started in the oral cavity and; • when the company provides the drug in line with the commercial access agreement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* A Resource Impact Template was not provided as NICE advised that it is anticipated that the guidance will not have a significant implication on resources. It is the view of local clinicians that approximately 4-5 patients per annum would be eligible for treatment with cetuximab under this guidance.
4.	**Patient Access Scheme Availability** **(<u>Yes</u>/**No**)** The pricing arrangement considered during guidance development was one in which the company (Merck) had agreed a patient access scheme with the Department of Health. This scheme would have provided a simple discount to the list price of cetuximab with the discount applied at the point of purchase or invoice. The Department of Health considered that this patient access scheme would not constitute an excessive administrative burden on the NHS. This has now been replaced by a commercial access agreement between the company and NHS England, which incorporates this same simple discount applied at the point of purchase or invoice of all cetuximab but also includes additional and separate commercial arrangements. The financial terms of the agreement are commercial in confidence.
5.	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Cetuximab is administered intravenously. The initial loading dose is 400 mg/m^2 body surface area (BSA) given at a rate not exceeding 5mg/minute. Subsequent weekly maintenance doses are 250mg/m^2 BSA each.

	The list price of cetuximab is £178.10 for a 5mg/ml 20ml vial and £890.50 for a 5mg/ml 100ml vial (excluding VAT). Assuming that vials are not shared among patients, a person with a body surface area of 1.75 m^2 would have 7 vials per loading dose and 5 vials per maintenance dose, equating to a cost of £1,246.70 for the loading dose and £890.50 for each maintenance dose. Thus, if a patient is treated for one year, the cost of cetuximab will be: • Loading dose (£1246.70) x1 plus maintenance doses (£890.50) x51 = • Total = £46,662.20 per patient per annum (before any discounts)
5.2	**Infrastructure costs 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.
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 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.