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

Health and Social Care Board

1.	**Treatment & Condition** Cetuximab and panitumumab for previously untreated metastatic colorectal cancer
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA439 (March 2017) Cetuximab is recommended, within its marketing authorisation, as an option for previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults in combination with: • 5‑fluorouracil, folinic acid and oxaliplatin (FOLFOX) or • 5‑fluorouracil, folinic acid and irinotecan (FOLFIRI). Panitumumab is recommended, within its marketing authorisation, as an option for previously untreated RAS wild-type metastatic colorectal cancer in adults in combination with: • FOLFOX or • FOLFIRI. The drugs are recommended only when the companies provide them with the discounts agreed in their patient access schemes. Prior to the publication of this NICE guidance, funding for these treatments in England was available through the Cancer Drugs Fund. In the absence of a similar Fund in Northern Ireland, these treatments were not routinely funded previously.
3.	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* According to the estimates made by NICE and using the assumptions in the Resource Impact template that accompanies TA439, there will be 89 patients in NI annually who will be eligible for treatment under this guidance. However, it is the view of local clinicians that the total number of patients eligible for cetuximab or panitumumab in the first year will be in the region of 112.
4.	**Patient Access Scheme Availability** **(Yes/**No**)** The Department of Health and the manufacturers of cetuximab and panitumumab (Merck Serono and Amgen) have agreed that cetuximab and panitumumab will be available to the NHS with a patient access scheme which makes it available with a discount. The size 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)** Cetuximab (Erbitux®) is given by intravenous infusion once a week. The first dose of cetuximab is 400 mg/m^2 body surface area. All further doses are 250 mg/m^2 of cetuximab given weekly. Cetuximab costs £178.10 per 100mg vial and £890.50 per 500mg vial (excluding VAT). The average dose per patient (based on an assumed body surface area of 1.79m^2) is: • 1.79 x 400 = 716mg for the first dose • 1.79 x 250 = 447.5mg for the second and subsequent doses The average cost per patient (based on an assumed body surface area of 1.79m^2) is: • £890.50 + (2 x £178.10) = £1246.70 for the first dose • £890.50 for the second and subsequent doses Assuming the average duration of treatment is 16 weeks, then the average cost of treatment per patient is £1246.70 + (15 x £890.50) = £14,604.20 Panitumumab (Vectibix®) is given by intravenous infusion once every 2 weeks at a dose of 6 mg/kg of body weight. Panitumumab costs £379.29 per 100mg vial and £1,517.16 per 400mg vial (excluding VAT) The average dose per patient (based on an assumed body weight of 80kg) is 80 x 6 = 480mg. Assuming no vial sharing, each dose costs £1896.45 Assuming the average number of treatment cycles is eight, then the average cost of treatment per patient is 8 x £1896.45 = £15,171.60
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. Clinicians have highlighted that given the introduction of a number of new therapies across oncology and haematology, there is increasing pressure on chair time, pharmacy, nursing and medical resources.
6.	**Expected implementation period** The implementation of this TA may be affected by the necessary infrastructure available as referenced in 5.2 above.

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.