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

Health and Social Care Board

1.	**Treatment & Condition** Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA478 (October 2017). Brentuximab vedotin is recommended as an option for treating relapsed or refractory systemic anaplastic large cell lymphoma (sALCL) in adults, only if: • they have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and; • the company provides brentuximab vedotin according to the commercial access agreement with NHS England. When using ECOG performance status, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect ECOG performance status and make any adjustments they consider appropriate.
3.	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* By extrapolation from the Resource Impact Statement that accompanies TA478, NICE estimate that around 5 people per year in Northern Ireland are estimated to be eligible and fewer than 2 people are anticipated to have brentuximab vedotin.
4.	**Patient Access Scheme Availability** **(<u>Yes</u>/**No**)** The Company (Takeda®) has agreed a commercial access agreement with NHS England in which a discount is applied at the point of purchase or invoice for brentuximab vedotin. 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)** The recommended dose of brentuximab vedotin is 1.8mg/kg administered by intravenous infusion over 30 minutes every 3 weeks. The Summary of Product Characteristics states that patients with relapsed or refractory sALCL who achieve stable disease or better should receive a minimum of 8 cycles and up to a maximum of 16 cycles.

	The list price of brentuximab vedotin is £2,500 for a 50mg vial (excluding VAT). Assuming an average body weight of 83.6kg and that 8-16 cycles are given: • Brentuximab dose = 1.8 x 83.6 = 150.48mg (rounded down to 150mg) • Cost per dose at list price (assuming no vial sharing) = 3 x £2,500 = £7,500 • Cost for 8 cycles = 8 x £7,500 = £60,000 • Cost for 16 cycles = 16 x £7,500 = £120,000 Therefore the average cost per patient is estimated to be between £60k and £120k at the list price.
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.