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

Health and Social Care Board

1	**Treatment & Condition** Panobinostat for treating multiple myeloma after at least 2 previous treatments.
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal Guidance (TA380). January 2016 Panobinostat in combination with bortezomib and dexamethasone is recommended, within its marketing authorisation, as an option for treating multiple myeloma, that is, for 'adult patients with relapsed and/or refractory multiple myeloma who have received at least 2 prior regimens including bortezomib and an immunomodulatory agent' when the company provides panobinostat 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)*

Number of people eligible for treatment in Northern Ireland

Population	**Proportion**	**Number of people**
Population of NI		1,840,498
Incidence of multiple myeloma	0.066%	122
People who choose to undergo treatment	70.40%	86
3 years survival rate as proxy for those eligible for at least 3rd line treatment	52.70%	45
Proportion of patients with ≥2 prior lines of treatment including an IMID and Bortezomib	80%	36
Uptake from year 2	30%	11

It is estimated that 7-9 people will be eligible for treatment with panobinostat in year 1 moving to 11 per annum from 17/18 onwards.

4	**Patient Access Scheme availability** The Department of Health and the manufacturer of panobinostat (Novartis) have agreed that panobinostat 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)** Panobinostat costs £776 per 20 mg tablet (list price). The recommended starting dose of panobinostat is 20 mg, taken orally once a day, on days 1, 3, 5, 8, 10 and 12 of a 21-day cycle. Patients should have panobinostat for 8 cycles, after which it is recommended that patients showing clinical benefit continue the treatment for 8 additional cycles. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of panobinostat, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. Cost per patient per cycle of treatment = £776 x 6 = £4,656 Cost per patient per initial 8 cycles of treatment = £37,248 NICE has not provided an estimate of number of patients who potentially will require more than 8 cycles. It is the view of local clinicians that this is not easy to forecast and therefore uptake of panobinostat will be closely monitored
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** The current in year costs will be covered via the cost per case arrangement.
5.4	**Recurrent overall costs per annum** *(including additional costs)* According to the Resource Impact Template that accompanies TA380 the recurrent overall costs per annum (before the application of any PAS discount) will be £177k
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 drug 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	**DHSSPS 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.